D.D.N.J., F.D.C. 6461–6480 Issued January 1962

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6461–6480

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *January 25, 1962.*

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

6461. (F.D.C. No. 41148. S. Nos. 77–573 M, 77–576/7 M.)

INFORMATION FILED: 3–24–58, M. Dist. Ga., against **Samuel J. DeFreese, M.D., Monroe, Ga.**

CHARGE: Between 8–7–57 and 8–22–57, *amphetamine sulfate tablets* were dispensed twice and *phenobarbital tablets* were dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 6–2–58, and was concluded on 6–10–58, with the return by the jury of a verdict of guilty. On 6–11–58, the court imposed a sentence of one years imprisonment on each of the 3 counts of the information for a total sentence of 3 years imprisonment. The defendant appealed the case to the United States Court of Appeals for the Fifth Circuit and, on 9–30–59, the following opinion was handed down by that court (270 F. 2d 737):

WISDOM, *Circuit Judge:* "The appellant, Samuel J. DeFreese, a physician, was indicted for violation of the Federal Food, Drug, and Cosmetic Act. 21 USCA 301 et seq. He was tried before a jury and found guilty on each of three counts. We affirm the conviction.

"Counts one and two of the information charged Dr. DeFreese with dispensing, without a prescription, dl-amphetamine[1] sulphate tablets in a bulk container. The third count charged Dr. DeFreese with a sale of phenobarbital tablets[2] without a prescription. The information alleged that these drugs had been shipped in interstate commerce; that the sales were in violation of 21 USCA 353(b)(1) and 331(k).

"The appellant practices in Monroe, Georgia. Wilbur R. Sumrall, Jr., an inspector for the Food and Drug Administration approached Dr. DeFreese on August 7, 1957 and inquired about purchasing 20,000 'bennies' (Benzedrine tablets). Sumrall posed as a truck driver and a 'pusher' or salesman of dl-amphetamine sulphate tablets. They drove to appellant's office in Monroe, Georgia. Appellant weighed out approximately 20,000 tablets on a scale and gave them to Sumrall. Sumrall paid him $200 for the tablets.

"Dr. DeFreese did not give Sumrall a physical examination nor did he consider Sumrall as a patient. He told Sumrall, in case he should be caught, to say that the tablets were 'just aspirin tablets'. Sumrall had a concealed portable wire recorder that recorded his conversation with DeFreese.

"On August 22, 1957, Sumrall, accompanied by another inspector for the Food and Drug Administration, made a second purchase of 20,000 dl-amphetamine sulphate tablets (Count two). He purchased also 1,000 phenobarbital tablets (Count three). In each case the amphetamine tablets were packed in a bulk container and bore labeling setting forth all the statutory information required by the Federal Food, Drug, and Cosmetic Act, including the name of the manufacturer, the name of the drug, the quantity of tablets, the strength of each tablet, dosage, the generally accepted warnings against misuse, and the prescription legend to the effect that Federal law prohibited its dispensing without prescription. The phenobarbital was repackaged and did not bear a label when sold.

I.

"The appellant contends, first, that the government failed to prove that the phenobarbital had been shipped in interstate commerce. 21 USCA 331(k).

"The government's proof of interstate shipment consisted of showing that the tablets were manufactured in a state other than Georgia, where they were sold. Dr. Albert H. Tillson, a microanalyst employed by the Food and Drug

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[1] Dl-amphetamine is a "dangerous drug" within the meaning of Section 353(b)(1)(B).
[2] Phenobarbital is a "habit-forming drug" within the meaning of Section 353(b)(1)(A), as defined by Section 352(d) and 21 C.F.R. 165.1.

Administration, testified that on the basis of scientific examination, microscopic markings, comparison with samples, and by other means, he determined that the tablets were manufactured by Excel Pharmacal Company of New York. This company has only one laboratory and it is located in New York City. The manager of Excel Company denied any sale to DeFreese.

"After an interstate shipment, it is immaterial when or how Dr. DeFreese obtained the drugs. United States v. Sullivan, 1948, 332 U.S. 689, 68 S. Ct. 331, 92 L. Ed. 297; Archambault v. United States, 10 Cir., 1955, 224 F. 2d 925. Since the tablets were manufactured outside the state of Georgia and sold by Dr. DeFreese in Georgia, the inference is inescapable that there was an interstate shipment.

"On appeal, but not during the trial, appellant makes the objection that it is impossible to tell whether Dr. Tillson testified as an expert or as one familiar with the facts; that his testimony was unscientific and entitled to no weight. The record discloses that Dr. Tillson has obtained three degrees in chemistry, belongs to an honorary scientific fraternity, and has had several articles published on microanalysis. His duties involve microscopic examination of foods and drugs in order to identify the ingredients and the manufacturing source of drug tablets. Whether a witness qualifies as an expert rests within the discretion of the trial court. Wharton, Criminal Evidence § 968 (11th ed. 1935). Here, there is no doubt that Dr. Tillson testified as an expert and that his testimony was admissible to show that the tablets were manufactured outside of Georgia. Aeby v. United States, 5 Cir., 1953, 206 F. 2d 296, cert. den. 346 U.S. 885, reh. den. 346 U.S. 917. No evidence was offered to contradict Tillson's method of identification. The jury deemed it sufficient to establish interstate shipment. There is substantial evidence to sustain the jury's verdict.

II.

"The appellant attempts to drag in the Jencks case, contending that the government should have furnished a machine for him to play back the wire recorder.

"Sumrall testified that he had concealed on his person a Minifone electronic wire recorder on which was recorded his conversation with DeFreese. Appellant's counsel moved for the agent's 'entire file and findings about Dr. DeFreese' for the purpose of impeachment and questioning, including the wire recording. Over objection of government counsel, relying on 18 USCA 3500,[3] the district court ruled that appellant's counsel was entitled to hear the recording. The recording was not played before the jury; it was played in chambers.

"Later, it was brought out on cross-examination that the original wire recording had not been delivered. Instead, a tape recording made from the original had been delivered to the appellant and played. Appellant's counsel then moved for inspection of the original. The government agreed and delivered the original wire recording, but did not furnish the machine necessary to play back the original. The government then placed two inspectors on the stand to testify that the Minifone wire recorder used by Sumrall was not the property of the United States, but had been rented by Sumrall and returned to the firm supplying it. Neither the government nor appellant's attorney could find a machine upon which the original wire could be played back. However, the record is clear that whatever was on the wire was transferred to the tape that was played back on the tape recorder. Further, the appellant was permitted to examine reports made by Sumrall, including a typewritten transcript of the recording. The Court afforded appellant ample time to listen to this tape, and also an opportunity to obtain a play-back machine, if one could be found.

"Appellant moved to suppress the evidence and for a judgment of acquittal, contending that denial of these motions constituted error and grounds for reversal under Jencks v. United States, 1956, 353 U.S. 657, 77 S. Ct. 1007,

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[3] In any criminal prosecution brought by the United States, Section 3500 requires the government to produce, for the defendant's inspection, any statement in the possession of the United States which was made by a government witness or prospective government witness. This statement can be demanded only after the witness has testified on direct examination, and it is limited to the subject matter as to which the witness testified.

1 L. Ed. 2d 1103. The Jencks case did not concern statements made by the defendant. It involved statements made by two undercover informants of the Federal Bureau of Investigation. These statements, or reports based on them, were in the possession of the government. In the instant case the government did not have in its possession a machine which could play the original wire recording.

"The Jencks rule does not require the government to furnish something it does not have and cannot obtain. Here, everything the government did have in its possession was turned over to the appellant, including a tape recording and transcript of the full original wire recording. This is all that justice and fairness require.

III.

"Appellant's third specification of error is that he was not allowed to introduce evidence showing the relative toxicity of amphetamine as compared with drugs that are legally sold without a prescription. Full proof of his contention would not excuse the sales by him of a drug that falls within the application of 18 USCA 353(b) (1) (B).

IV.

"The appellant's final contention is that 18 USCA 353(b) (1) does not apply to wholesale transactions but only to sales to individual consumers. The same contention was answered by this Court in Sam and Martha DeFreese v. United States, No. 17, 361.

"Judgment is AFFIRMED."

The defendant filed a petition of a writ of certiorari with the United States Supreme Court on 12–30–59, and on 4–4–60 such petition was denied.

6462. (F.D.C. No. 41147. S. Nos. 77–570 M, 77–572 M.)

INFORMATION FILED. 4–4–58, N. Dist. Ga., against **Samuel J. DeFreese, M.D., and his wife, Marsha Jean Simmons DeFreese, Duluth, Ga.**

CHARGE: Between 7–26–57 and 8–1–57, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 7–14–58, and was concluded on 7–16–58, with the jury's return of verdicts of guilty. On 7–22–58, the court imposed a sentence of 1 years imprisonment against each defendant. The defendants appealed the case to the United States Court of Appeals for the Fifth Circuit and on 9–30–59, the following opinion was handed down by that court (270 F. 2d 730):

WISDOM, *Circuit Judge:* "This appeal raises a serious question as to whether the Federal Food, Drug, and Cosmetic Act,[1] prohibiting dispensing of certain potentially dangerous drugs without a prescription, applies only to sales at the retail or pharmacist's level. We hold that it applies to bulk sales for resale by a physician, in the circumstances of this case. The appellants raise other points, all of which we consider without merit. We affirm, therefore, the judgment of the district court.

I.

"The appellants are husband and wife, not long married. Samuel J. DeFreese practiced medicine for twelve years in Monroe, Georgia. Marsha Jean DeFreese owned and operated a restaurant, Jean's Fine Foods, near Duluth, Georgia, on U.S. Route 23, a route well traversed by long-distance truck drivers.

"About eight in the evening of July 26, 1957, Wilbur R. Sumrall, a food and drug inspector posing as a former truck driver, visited Jean's Fine Foods. He asked for Dr. DeFreese. Mrs. DeFreese said that her husband was not in the

[1] 21 USCA 301–392.

restaurant. She joined Sumrall at a table and started a conversation. He identified himself as 'Bud,' a truck driver. During their conversation Mrs. DeFreese spilled some coffee and blamed it on having taken three 'bennies' [2] that afternoon to stay awake. Sumrall told her that a friend in Tallahassee, Florida, had sent him to her because he was in the market for several thousand Benzedrine tablets. He asked if she had them and what the price would be. After she quoted the price, Sumrall said he would buy 5,000. Mrs. DeFreese went upstairs. After a few minutes she came back to the table and told Sumrall that she had placed the tablets on the third step at the other end of the dining room. Sumrall paid her $75. She told him that she knew of some people in south Georgia who would take some of the tablets off his hands. Sumrall told Mrs. DeFreese he would return when he had disposed of the tablets. She wrote down her name and telephone number on a slip of paper and told him to call her before coming again and not to bring anyone with him.

"Sumrall picked up the package and left. He drove down the highway a short distance where he met two other Food and Drug Inspectors. The package was marked and turned over to them. The package contained approximately 5,000 Benzedrine tablets.

"Sumrall did not give a prescription to Mrs. DeFreese for the 5,000 tablets. No one made a physical examination of him or asked him any questions about his medical history. Dr. DeFreese was not present at any time during the first meeting between Sumrall and Mrs. DeFreese. Only Mrs. DeFreese was convicted on the count of the information that set forth this transaction.

"Both appellants were convicted on the second count for a transaction that took place on July 31, 1957. That afternoon Sumrall telephoned Mrs. DeFreese from Phenix City, Alabama, identifying himself as 'Bud' Sumrall from Tallahassee. He said he was doing a little 'selling,' and he wanted to come up that night and buy 10,000 Benzedrine tablets. They arranged to meet at the restaurant. When Sumrall arrived at the restaurant only Dr. DeFreese was there. Sumrall asked if 'Jean' (Mrs. DeFreese) were there. Dr. DeFreese told him that the girls had gone to town. Dr. DeFreese said that Mrs. DeFreese had mentioned that someone was coming up that night and asked Sumrall if he were the one. They introduced themselves. Sumrall told Dr. DeFreese that he would like to buy 'the stuff' and get on the road.

"Dr. DeFreese went upstairs for the 10,000 tablets that Sumrall requested. He returned without them because the room where they were kept was locked. Mrs. DeFreese had the key. She returned around one in the morning. Dr. DeFreese told her that Sumrall was in a hurry and that he had not given him the tablets because the room was locked. Sumrall told her he wanted 10,000. She left the room and when she returned he paid her $150 in the presence of Dr. DeFreese. Sumrall walked through the dining room and picked up a package, again on the steps. He drove to his residence with the package where he met another Food and Drug Inspector. The package was marked. It contained approximately 10,000 Benzedrine tablets.

"The criminal information upon which both appellants were convicted charged that on July 26, 1957, Mrs. Marsha Jean DeFreese, and on August 1, 1957, both Mrs. DeFreese and Dr. Samuel J. DeFreese, dispensed a number of dl-amphetamine sulphate (Benzedrine) tablets to Wilbur R. Sumrall, Jr. without a prescription, in violation of 21 USCA 353(b)(1) and 21 USCA 331(k).[3]

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[2] "Bennies" is a slang expression used to describe Benzedrine, a brand name for amphetamine.

[3] 21 USCA 353(b)(1) provides:

"A drug intended for use by man which—
(A) is a habit-forming drug to which section 352(d) of this title applies; or
(B) because of its toxicity or other potentiality for harmful effect or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
(C) is limited by an effective application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug, shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing

"Dr. DeFreese denied any sale of the drug to Sumrall. Mrs. DeFreese admitted the first sale but denied the second.

"Appellants were tried together on this information before a jury. They were found guilty and sentenced to one year on each count, the sentences for Mrs. DeFreese to run concurrently.

II.

"Appellants argue that Section 353(b)(1), for the violation of which they were convicted, is concerned solely with sales of drugs at the retail or pharmacist's level.[4] The statute reads, in part, that certain categories of drugs

> . . . shall be dispensed only (1) upon the written prescription of a practitioner licensed by law to administer such drug, or (2) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (3) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. [Italics supplied.]

It is contended therefore that the violation arises out of the dispensing of such drugs without a prescription. Thus, the same subsection of the statute goes on to say:

> The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held by sale. [Italics supplied.]

Appellants argue then that the reference to 'prescription' indicates that the statute refers only to pharmacists' sales at the retail level to consumers.[5] Otherwise manufacturers or jobbers would be guilty of violating the law if they placed the drugs in the ordinary channels of trade by selling to a drugstore without a prescription.

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a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale."

21 USCA 331(k) provides:

"The following acts and the causing thereof are hereby prohibited:

* * * (k) The doing . . . of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded."

21 USCA 333 provides the penalty for violation of any provision of Section 331. The amphetamine sulphate tablets which were sold fall within the scope of 21 USCA 353 (b)(1)(B) in that it was a drug intended for the use of man which is not safe for use except under the supervision of a practitioner licensed by law to administer such drug.

[4] There is superficial support for this position. Thus, Federal Security Administrator Ewing, in his statement to the House Committee, supra, stated: "The bill which is before you, H.R. 3298, deals with the retail sale of drugs that have previously moved in interstate commerce and are thus subject to federal regulation." (Italics supplied) Mr. N. E. Cook, Assistant to the Commissioner, Food and Drug Administration, in an address at Temple University School of Pharmacy, March 9, 1953 (reported in Food, Drug, Cosmetic Law Journal, Vol. 8, No. 5 (May, 1953) p. 327) opened his remarks: "The direct application of the Federal Food, Drug and Cosmetic Act to the practice of pharmacy is principally in the provisions of the Durham-Humphrey amendment." Mr. James F. Hoge, an industry attorney, writing in the same journal (Vol. 6, No. 2 (Feb. 1951) p. 135), points out: "The bill had its origin in a situation wherein retail druggists perceived a need of clarification either in the law or the administration of the law, or both, with respect to the filling and refilling of prescriptions."

[5] Appellants quote Remington's Practice of Pharmacy, (11 ed. 1956), p. 1413, in which the term "prescription" is defined as "the formula which a physician writes, specifying the substance or substances he intends to have administered to a patient with adequate directions for use." In Brown v. United States, 1958, 5 Cir., 250 F. 2d 745, however, holding that the Act applies to a licensed physician dispensing drugs, this Court pointed out: "The language of the statute considered alone, is certainly broad enough to make criminal what was done here [a doctor dispensing 3,000 pills to 'purchaser' who was not 'patient'] . . . The 3,000 tablets were acquired by the 'purchasers,' who were not 'patients,' without even a written or oral prescription, no matter how broadly the word 'prescription' is to be construed." In defining "prescription" under the Harrison Narcotic Act, 26 USCA 2550 et seq., Webb v. United States, ——, 249 U.S. 96, 39 S. Ct. 217, 63 L. Ed. 479, establishes as a criterion the requirement that the physician's order for the drug (in that case morphine) be "issued by him in the

"Appellants cite a number of decisions.[6] None draw a line between retail and wholesale sales. The best appellants can say for these decisions is that in each case a relatively small number of tablets were sold and obstensibly the drugs were for personal use. There is no language in any of the cases indicating that the court regarded the provisions of the Act as applicable only to retail sales.

"In one of the cases relied on by appellants, United States v. Carlisle, 5, Cir., 1956, 234 F. 2d 196, 199, the language of the court indicates that any dispensing of a drug contrary to the provisions of the act is prohibited:

> It [Congress] did this by setting out in 353(b)(1) the only way in which drugs of the kind dealt with can be dispensed, and then in the same section going on to say that the act of dispensing such a drug, contrary to the provisions of the paragraph, shall be deemed to be an act which results in the drug being misbranded. This established, by law in this section, there is required only resort to 21 USCA § 331(k), which denounces the offense of misbranding and to § 333, which fixes the penalty for that offense. When this resort is had, the conclusion is inescapable, we think, that the sections taken together have provided as clearly as though it had all been written out in the same section, that one dispensing drugs of the kind dealt with here, contrary to the provisions of Sec. 353(b)(1) shall be guilty of, and subject to the punishment provided by law for, an act of misbranding. This necessarily results from the use in Sec. 353(b)(1) of the language, 'the act . . . shall be deemed to be an act which results in the drug being misbranded while held for sale.'

"Brown v. United States, 5 Cir., 1958, 250 F. 2d 745, cert. den., 356 U.S. 938, 78 S. Ct. 779, 2 L. Ed. 2d 812, reh. den., 357 U.S. 933, 78 S. Ct. 1368, 2 L. Ed. 2d 1376, controls the disposition of the present case. In the Brown case this Court held that the Act applies to a licensed physician selling amphetamine tablets without a prescription, and not just to pharmacists. Able counsel for appellants attempt to distinguish the Brown case on the ground that Dr. Brown sold in the capacity of a pharmacist,[7] and that no question was raised as to the limitation of the Act to retail sales. In the Brown case there were three separate sales, each of 1,000 tablets, on March 10, 22, and 23. It is obvious that one person would not consume 3,000 tablets over such a short period of time; that the purchaser was not being treated as a patient or as a consumer making a retail purchase. We rested our decision on broad interpretation of the Act in the light of its objectives.

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course of professional treatment." Perhaps, the best definition is found in one of the most widely used standard textbooks on the science of pharmacology, entitled, "The Pharmacological Basis of Therapeutics" by Goodman & Gilman, 2d Ed. (1955): A prescription, by strict definition, is a physician's written order to a pharmacist for medicinal substances for a patient. It includes directions to the pharmacist regarding the preparation and to the patient regarding the use of the medicine.

In reality, however, a prescription is infinitely more than can be simply defined. It is a summary of the physician's diagnosis, prognosis, and treatment of the patient's illness. It brings to a focus on one slip of paper the diagnostic acumen and therapeutic proficiency of the physician. The prescription is an important practical phase in the application of pharmacology to clinical medicine, and combines the knowledge of the absorption, fate, excretion, action, toxicology, and dosage of drugs with the requirements for restoration of the patient's health. (p. 1759).

[6] United States v. Arnold's Pharmacy, Inc., D.C.N.J., 1953, 116 F. Supp. 310; Archambault v. United States, 10 Cir., 1955, 224 F. 2d 925; United States v. Carlisle, 5 Cir., 1956, 234 F. 2d 196; United States v. 2000 State Drugs, Inc., 7 Cir., 1956, 235 F. 2d 913, appeal denied 353 U.S. 848; Marshall v. United States, 10 Cir., 1958, 258 F. 2d 94, reversed on other grounds 27 U.S. Law Week 4439 (June 19, 1959). In United States v. Arnold's Pharmacy, Inc., a corporation, its treasurer and manager, and its pharmacist were convicted for selling drugs without a prescription, but nothing in the case indicates whether the sale was retail or wholesale. In Archambault v. United States; United States v. Carlisle; and United States v. 2000 State Drugs, Inc., the quantities sold are not stated.

[7] It has always been the rule that a physician who does his own dispensing is also acting in the capacity of a pharmacist. See Food and Drug Administration Trade Correspondence 174 (Mar. 14, 1940) published in Kleinfeld and Dunn, Federal Food, Drug, and Cosmetic Act, p. 637.

"The Federal Food, Drug, and Cosmetic Act was adopted in 1938.[8] Section 353(b)(1), in its present form, is the result of a 1951 amendment to the Act.[9] The purpose of the amendment was to accomplish two broad objectives: (1) To protect the public from abuses in the sale of potent prescription drugs; (2) to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are sold for use without the supervision of a physician. House Report No. 700, July 16, 1951, 2 Cong. Serv., 82nd Cong., First Sess. 1951, p. 2454. House Report No. 700 explains the amendment at page 2456: 'Its provisions are remedial in the sense that they are intended to protect the public from abuses in the sale of potent prescription medicines.' If we should adopt the appellants' argument, it would be impossible to accomplish the objective of the amendment. The protection afforded the general public would be dangerously diminished if a person making small retail sales without a prescription may be prosecuted while a person making large wholesale sales of drugs could not be prosecuted for selling without a prescription. We find it impossible to read such a result in the language of the statute or in its legislative history.

"The Act as a whole has been liberally construed. In United States v. Sullivan, 332 U.S. 689, 68 S. Ct. 331, 92 L. Ed. 297, it was held that the Act applied to any sale after interstate shipment and not just the first sale immediately following interstate shipment. In United States v. El-O-Pathic Pharmacy, 9 Cir., 1951, 192 F. 2d 62, 75, what the court said applies equally well here: 'The statute is remedial and should be liberally construed so as to carry out its beneficent purposes. . .' The appellants' contention that the amendment applies only to wholesale sales would violate the normal rules of statutory construction as well as the spirit of the entire Act. Other portions of the Act apply to wholesale situations. Section 373 requires carriers and persons receiving shipments to keep records. Section 374 allows inspection of warehouses, factories, or establishments where drugs are manufactured, processed, packed, or held, for introduction into interstate commerce. In United States v. Herold, D.C. N.Y., 1955, 136 F. Supp. 15, the defendant, who was charged with dispensing drugs without a prescription in violation of Section 331(k), contended that Section 374 allowed only inspections of factories and warehouses. The court rejected this attempt to construe narrowly the applicabiilty of the Act and held that Section 374 allowed inspections of drug stores as well. In Arner Co., Inc. v. United States, 1 Cir., 1944, 142 F. 2d 730, cert. den., 323 U.S. 730, it was contended that the labeling provisions of the Act applied only to retail sales. The court held that it also applied to bulk sales.

"The comprehensive scope of the entire Act was pointed to in United States v. Devices, 10 Cir., 1949, 176 F. 2d 652, 654:

> The purpose of the Act is to safeguard the consumer by applying its requirements to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer . . .

"Appellants' contention that the amendment applies only to retail sales is, in effect, predicated upon the assumption that the 1951 amendment is to be read alone and not in context with the rest of the Act. However, to read the amendment alone would render it nugatory because it contains neither a prohibitive or a penal clause. It would become meaningless unless construed with the rest of the Act. The amendment simply states that dispensing a drug contrary to its provisions shall be deemed to be an act which results in the drug being misbranded while held for sale. It is Section 331(k) that prohibits misbranding, and Section 333 that sets forth the penalty for misbranding. Section 331(k) applies to any act of misbranding. The plain language of the Act therefore covers all sales.

"Even if Section 353(b)(1) is read alone it will not support appellants' contention that the section is inapplicable to wholesale sales. The section lists three types of drugs and provides that they shall be dispensed in one

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[8] 52 Stat. 1040.

[9] The Durham-Humphrey Bill (H.R. 3298) amended Section 503(b) of the original Act to its present form as it now appears in 21 USCA 353(b)(1). Act 215, c. 578, Sec. 1, 65 Stat. 648.

of three stated methods, all of which require a prescription. Dispensing a drug contrary to these provisions is misbranding. The language is clear. The only way that appellants' contention could be sustained would be to interpret 'dispensing' to connote retail selling only. Such an interpretation would not be consistent with the commonly accepted meaning of the term and would be carving out an unwarranted exception to the statute. It is not the duty of this court to read exceptions into a statute that is plain on its face.

"In related fields of prohibitive conduct the court has rejected such a narrow interpretation as that offered by appellants in this case. A statute which prohibited the sale of narcotics without a written order [10] has been interpreted to apply to all persons making such sales. Taylor v. United States, 8 Cir., 1956, 229 F. 2d 826, cert. den., 351 U.S. 986; Nigro v. United States, 1928, 276 U.S. 332, 48 S. Ct. 388, 72 L. Ed. 600.

"Appellants argue that if Section 353(b)(1) applies to sales other than retail sales pharmaceutical houses and drug companies should also be prosecuted for selling drugs without a prescription. We are not faced with this issue here. However, the statute gives the Secretary of Health, Education, and Welfare broad powers to make exemptions to the requirements of the Act. Section 533(b)(3) empowers the Secretary to issue regulations removing 'habit-forming drugs' [11] and 'new drugs' [12] from the requirements of Section 353(b)(1) when such requirements are not necessary for the public health. Pursuant to this authority, the Secretary has provided exemptions from the prescription-dispensing requirements for certain habit-forming drugs. 21 CFR 1.108(a). Exemptions have also been made for certain new drugs. 21 CFR 1.108(c). Drugs within the legitimate channels of distribution are exempted from certain labeling requirements of the Act. 21 CFR 1.106(b)(1). As we read the regulations, as a whole, we interpret them as properly exempting wholesale distribution of amphetamine from the prescription requirements of Section 353(b)(1), when the drug is distributed in ordinary channels of trade, i.e. sales to physicians, pharmacists, and drug stores without the necessity of a prescription. For example, United States v. El-O-Pathic Pharmacy, 9 Cir., 1951, 192 F. 2d 62, 75, involved an injunctive suit to prohibit violations of various sections of the Federal Food, Drug, and Cosmetic Act. It was argued that the only power conferred upon the Administrator [13] was the authority to issue regulations exempting drugs from the requirement of 'adequate directions for use,' when that requirement 'is not necessary to the protection of the public health.' The court held that the Administrator also had the power to issue regulations providing the drugs be exempted from the requirement of adequate directions for use provided that the label state that the drug be used only on the prescription of a physician. If the regulations may require that a drug be sold on a prescription or contain adequate directions for use, it is well within the scope of authority of the Secretary to make exemptions from the prescription-dispensing requirements where the drugs are sold within the legitimate channels of wholesale distribution.

"In short, the fact that the crime in this case is wholesale, instead of retail, gives it no special claim to immunity.

III.

"We have considered carefully all of the specifications of errors in this case.

"A. We find that the trial court did not err in failing to dismiss the information against Dr. DeFreese on the ground that the evidence did not connect him with the transaction charged in the information.

"B. We find that the trial court did not err in refusing to grant the motion for separate trials for the defendants. There was no prejudice to either.

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[10] 26 USCA 2554(a), I.R.C. of 1939.

[11] "Habit-forming drugs" are those containing any quantity of the substances set forth in 21 USCA 353(d).

[12] "New drugs" are those described in 21 USCA 355.

[13] Prior to the creation of the office of Secretary of Health, Education, and Welfare, the Federal Security Administrator was empowered to issue regulations concerning the Federal Food, Drug, and Cosmetic Act.

"C. The defendants viewed a fair trial.

"D. The trial court correctly held that there should not be a mistrial based on counsel for the government characterizing Dr. DeFreese as a criminal. The court stated that he did not understand the United States Attorney to call Dr. DeFreese a criminal, 'but if so then I instruct the jury to disregard it, it would be improper if he did call Dr. DeFreese [a criminal].'

"Judgment is AFFIRMED."

The defendants filed a petition for a writ of certiorari with the United States Supreme Court on 12–30–59, and on 4–4–60, such petition was denied.

6463. (F.D.C. No. 44354. S. Nos. 3–244 P, 72–311 P, 72–494 P.)

INDICTMENT RETURNED: 8–9–60, M. Dist. Ga., against **Lee Roy Carter, Loganville, Ga.**

CHARGE: Between 9–29–59 and 10–15–59, *amphetamine sulfate tablets* were dispensed once and *desoxyephedrine hydrochloride tablets* were dispensed twice without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 12–7–60, and was concluded on the same day with the return of a verdict of guilty by the jury, at which time the defendant was placed on probation for 5 years.

6464. (F.D.C. No. 44632. S. Nos. 56–379 P, 57–200 P, 72–291 P, 72–481 P.)

INDICTMENT RETURNED: 10–3–60, N. Dist. Ga., against **Sterling Lee Wilkie (an employee of a truck stop at Cumming, Ga.).**

CHARGE: Between 8–28–59 and 9–3–59, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–20–60. 2 years probation.

6465. (F.D.C. No. 44630. S. Nos. 3–259 P, 87–601/2 P.)

INDICTMENT RETURNED: 8–9–60, M. Dist. Ga., against **Jesse McGee Garrett, t/a Gold Mine Truck Stop, Royston, Ga.**

CHARGE: Between 11–6–59 and 11–11–59, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 12–6–60. $100 fine and 5 years probation.

6466. (F.D.C. No. 44621. S. Nos. 56–378 P, 57–199 P.)

INDICTMENT RETURNED: 11–7–60, N. Dist. Ga., against **Marvin Lamar Brown (an employee of a truck stop near Gay, Ga.).**

CHARGE: On 8–26–59, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 11–22–60. Defendant placed on probation for 2 years.

6467. (F.D.C. No. 44352. S. Nos. 71–931 P, 72–497 P.)

INDICTMENT RETURNED: 11–9–60, N. Dist. Ga., against **Earl Eldredge Baker (an employee of a truck stop located near Calhoun, Ga.).**

CHARGE: On 10–8–59, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 11–21–60. Defendant sentenced to serve 1 year in jail.

6468. (F.D.C. No. 44928. S. Nos. 73–715 P, 73–717/8 P.)

INFORMATION FILED: 11–26–60, N. Dist. Miss., against **Manciel Carter (manager of a truck stop at Olive Branch, Miss.), and Claude Sexton (an employee).**

CHARGE: Between 10–7–59 and 10–24–59, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty by Carter to dispensing *amphetamine sulfate tablets* twice and by Sexton to dispensing such tablets once.

DISPOSITION: 3–17–61. Each defendant placed on probation for 2 years.

6469. (F.D.C. No. 45218. S. Nos. 44–169 P, 56–404/5 P, 56–414/5 P.)

INFORMATION FILED: 2–21–61, S. Dist. Ga., against **Lucille Studstill Cranford, t/a Camden Medicines, Camden County (Kingsland), Ga., and James Clifford Cranford (pharmacist.)**

CHARGE: Between 3–4–59 and 3–18–59, *amphetamine sulfate tablets* were dispensed 4 times and *pentobarbital sodium capsules* were dispensed once without a prescription.

PLEA: Nolo contendere by each defendant.

DISPOSITION: 3–20–61. The court fined Lucille Cranford $250 and James Cranford $750, and placed each defendant on probation for 5 years with the provision that the defendants should terminate all interests which they had in the Kingsland store of Camden Medicines.

6470. (F.D.C. No. 45217. S. Nos. 46–553 P, 46–558 P, 46–606 P, 74–045 P.)

INFORMATION FILED: 2–13–61, N. Dist. Ala., against **Chris P. Hausman, M.D., Tuscaloosa, Ala.**

CHARGE: Between 10–12–59 and 10–29–59, *amphetamine sulfate tablets* were dispensed twice and *dextro-amphetamine sulfate tablets* and *desoxyephedrine hydrochloride tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 3–29–61. $500 fine.

6471. (F.D.C. No. 45196. S. No. 29–197 P.)

INFORMATION FILED: On or about 2–13–61, M. Dist. Ala., against **Alvin M. Brown, t/a Panorama Truck Stop, Camp Hill, Ala.**

CHARGE: On 9–2–59, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–21–61. Probation for 3 years.

6472. (F.D.C. No. 45193. S. Nos. 29–317 P, 46–530/1 P, 46–540 P.)

INFORMATION FILED: On or about 2–13–61, M. Dist. Ala., against **Arthur W. Hinton and Charles Lee True (employees of a truck stop at Montgomery, Ala.).**

CHARGE: Between 6–12–59 and 8–11–59, *amphetamine sulfate tablets* were dispensed twice without prescription.

PLEA: Guilty by Hinton to count 2 of the information and not guilty by True to count 1.

DISPOSITION: The case against True came on for trial before the court and jury on 4–20–61, and was concluded with the return of a verdict of guilty by the jury. On 4–21–61, the court imposed sentences of 6 months in jail against Hinton and 4 months in jail against True.

6473. (F.D.C. No. 44345. S. Nos. 3–248 P, 71–934 P, 72–503 P.)

INDICTMENT RETURNED: 11–9–60, N. Dist. Ga., against **James Frank Parker, Sr., t/a Twin Tanks Truck Stop, Fairmount, Ga.**

CHARGE: Between 10–14–59 and 10–23–59, *desoxyephedrine hydrochloride tablets* were dispensed 3 times without prescription.

PLEA: Guilty.

DISPOSITION: 11–29–60. Defendant fined $150 and placed on probation for 2 years.

6474. (F.D.C. No. 45198. S. Nos. 79–261/7 P, 79–269 P.)

INFORMATION FILED: 2–8–61, E. Dist. Mich., against **Leonard A. Castiglione, Jr., t/a Gratiot Pharmacy, Detroit, Mich.**

CHARGE: Between 8–27–59 and 10–28–59, *Zenobese 15 capsules* (consisting of amphetamine sulfate, thyroid, phenobarbital, and other ingredients) were dispensed 5 times, *Achromycin V capsules* were dispensed twice, and *dextro-amphetamine sulfate capsules* were dispensed once without prescription.

PLEA: Guilty.

DISPOSITION: 4–4–61. $2,000 fine and probation for 2 years.

6475. (F.D.C. No. 45211. S. Nos. 23–178/82 R, 23–576 R, 23–578/80 R.)

INFORMATION FILED: 2–16–61, W. Dist. Okla., against **Asa R. Maley and Arthur Talley (pharmacist and employee respectively of a drug store at Sayre, Okla.).**

CHARGE: Between 4–1–60 and 5–2–60, *meprobamate tablets* were dispensed 3 times without a prescription, and *dextro-amphetamine sulfate tablets* and *pentobarbital sodium capsules* were each dispensed 3 times upon request for refills of prescriptions without authorization by the prescribers.

PLEA: Guilty by each defendant.

DISPOSITION: 4–24–61. Each defendant fined $300.

6476. (F.D.C. No. 43214. S. Nos. 1–211 P, 1–216/7 P, 1–430/1 P, 1–518 P, 1–540 P, 1–542 P, 44–017 P, 56–300 P, 56–321/2 P.)

INFORMATION FILED: 7–21–59, S. Dist. Ga., against **Joseph W. Brooks and Everett E. Garvin (pharmacists), Savannah, Ga.**

CHARGE: Between 9–10–58 and 1–19–59, *Dexedrine Sulfate tablets* were dispensed 6 times (counts 1 to 5, incl., and 9) and *Nembutal capsules* were dispensed 4 times (counts 6 to 8, incl., and 11) upon request for prescription refills without authorization by the prescriber, and *Nembutal capsules* (count 10) and *Dexedrine Sulfate tablets* (count 12) were each dispensed once without a prescription.

PLEA: Nolo contendere by Garvin to counts 1 to 4, incl., and 6 and 7, and guilty by Brooks to counts 5, and 8 to 12, incl.

DISPOSITION: On 11–16–59, Brooks was sentenced to 2 years imprisonment with sentence suspended upon payment of a $300 fine within 30 days; on 3–15–60, Garvin was sentenced to 1 years imprisonment with sentence suspended and placed on probation for 2 years.

6477. (F.D.C. No. 44661. S. Nos. 57–204 P, 72–489 P.)

INFORMATION FILED: 9–13–60, S. Dist. Ga., against **Ellsworth O. Fish (an employee of a restaurant on U.S. Highway No. 301, in Long County, Ga.).**

CHARGE: On 9–21–59, *amphetamine sulfate tablets* were dispensed twice without a prescription.

DISPOSITION: On 2–9–61, the case was transferred to the Southern District of New York for the entry of a plea of guilty. On 3–6–61, the defendant entered a plea of guilty and was placed on probation for 6 months.

6478. (F.D.C. No. 43701. S. Nos. 53–345 P, 53–579 P, 53–581/2 P.)

INFORMATION FILED: 1–29–60, Dist. Nev., against **Nicholas Eugene Thomsen, t/a Nick's Drug, Las Vegas, Nev.**

CHARGE: Between 7–23–59 and 8–13–59, *secobarbital sodium capsules* were dispensed once and *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 6–24–60. Imprisonment for 1 year.

6479. (F.D.C. No. 43723. S. Nos. 45–884/7 P, 45–889/93 P.)

INFORMATION FILED: 3–1–60, N. Dist. Miss., against **James W. Listenbee, t/a Listenbee's Drug & Dept. Store, Calhoun City, Miss.**

CHARGE: Between 1–20–59 and 1–27–59, *phenobarbital tablets* were dispensed 3 times, *prednisone tablets* were dispensed twice, and *penicillin tablets*, *thyroid tablets*, *Tuinal capsules*, and *meprobamate tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 5–27–60. $900 fine.

6480. (F.D.C. No. 45204. S. Nos. 29–173/5 R, 29–177/8 R, 29–939 R, 29–942/4 R.)

INFORMATION FILED: 1–24–61, S. Dist. Iowa, against **Otis C. Webb, Jr., t/a Douglas Pharmacy, Des Moines, Iowa.**

CHARGE: Between 9–9–60 and 9–14–60, *phenobarbital tablets* were dispensed twice upon requests for prescription refills without authorization by the prescriber, and *amphetamine sulfate tablets* were dispensed 6 times and *methyltestosterone tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2–20–61. Imprisonment for 1 year.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 6461 TO 6480

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (6461, 6462) Prosecution contested. Contains opinion of the court.
[2] (6463, 6472) Prosecution contested.

[2] (6463, 6472) Prosecution contested.

U.S. GOVERNMENT PRINTING OFFICE: 1962

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6481–6500

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent; (2) a criminal proceeding terminated upon a plea of guilty; and (3) an injunction proceeding terminated upon the entry of a permanent injunction by consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *March 23, 1962.*

CONTENTS*

*For presence of a habit-forming substance without warning statements, see No. 6481; an imitation of, and sale under name of, another drug, No. 6482; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 6484.

629973—62——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6481–6500

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, or its quality fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; and Section 503(b)(1), the article was dispensed without a prescription from a practitioner licensed by law to administer the article.

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6481. Delfetamine Stedytabs and Delfeta-Sed Stedytabs. (F.D.C. No. 44603. S. Nos. 4–020/1 R.)

QUANTITY: 2 drums, each containing about 50,000 tablets, and 118 30-tablet ctns., of *Delfetamine Stedytabs*, and 278 30-tablet ctns., of *Delfeta-Sed Stedytabs*, at Baltimore, Md., in possession of Eastern Research Laboratories, Inc.

SHIPPED: Between 11–16–58 and 3–21–60, from St. Louis, Mo., by Victor M. Hermelin & Co.

LABEL IN PART: (Drum) "Delfetamine, 30 Mg. Stedytabs Each tablet contains: *Delfatamine 30 mg. Caution * * * Average dose * * * Manufactured by a special process * * * to provide prolonged continuous therapeutic effect from active ingredient over a period up to 8–12 hours. *Registered Trademark of dl-N-methyl-beta-phenylisopropylamine Hydrochloride. Victor M. Hermelin and Company, New Products Division of K–V Pharmacal Company, St. Louis 17, Missouri"; (ctn.) "Stedytabs Sustained Release Tablets Delfetamine dextro-levo N-methylamphetamine HCl * * * Eastern Research Laboratories, Inc., Baltimore 1, Maryland"; and "Stedytabs Sustained Release Tablets Delfeta-sed Delfetamine With Sedafax * * * Eastern Research Laboratories, Inc., Baltimore 1, Maryland."

RESULTS OF INVESTIGATION: Examination showed that the articles contained (*Delfetamine Stedytabs*) methamphetamine HCl, and (*Delfeta-Sed Stedytabs*) methamphetamine HCl and amobarbital. The tablets in the cartons were repacked by the dealer from bulk stock shipped as described above.

LIBELED: 6–3–60, Dist. Md.

CHARGE: 502(d)—while held for sale, the *Delfeta-Sed Stedytabs* contained a habit forming drug, amobarbital, a derivative of barbituric acid, and their label failed to bear the name of the drug and in juxtaposition therewith the statement "Warning—May be habit forming"; and 505(a)—the *Delfetamine Stedytabs* and the *Delfeta-Sed Stedytabs* were new drugs which may not be introduced into interstate commerce since applications filed pursuant to the law were not effective with respect to such drugs.

DISPOSITION: 8–8–60. Default—destruction.

6482. Meprobamate tablets, chlorothiazide tablets, and hydrochlorothiazide tablets. (F.D.C. No. 44875. S. Nos. 4–661/2 R, 4–664 R.)

QUANTITY: Unknown quantities of the above-mentioned drugs at Washington, D.C., in possession of Discount Drugs.

LIBELED: 8–30–60, Dist. Columbia.

CHARGE: *Meprobamate tablets*, 502(i)(2)—while in interstate commerce, the article was an imitation of another drug, namely, Miltown tablets; and 502(i)(3)—the article was offered for sale under the name of another drug, namely, Miltown tablets.

Chlorothiazide tablets, 502(i)(2)—while in interstate commerce, the article was an imitation of another drug, namely, Diuril tablets; and 502(i)(3)—the article was offered for sale under the name of another drug, namely, Diuril tablets.

Hydrochlorothiazide tablets, 502(i)(2)—while in interstate commerce, the article was an imitation of another drug, namely, Hydrodiuril tablets; and 502(i)(3)—the article was offered for sale under the name of another drug, namely, Hydrodiuril tablets.

All articles, 505(a)—the articles were new drugs which may not be introduced into interstate commerce since applications filed pursuant to 505(b) were not effective with respect to such drugs.

DISPOSITION: 10–5–60. Default—delivered to the Food and Drug Administration.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

6483. Phenobarbital tablets and amphetamine sulfate tablets. (F.D.C. No. 44941. S. Nos. 61–603/6 P, 61–608/12 P, 61–614 P, 61–616/8 P.)

INFORMATION FILED: 11–28–60, N. Dist. Ohio, against William H. Caine, M.D., Antwerp, Ohio.

SHIPPED: Between 5–30–59 and 7–18–59, from Ohio to Michigan.

CHARGE: 502(f)(1)—when shipped, the labeling of the articles failed to bear adequate directions for use for the purposes and conditions for which they were intended; and 503(b)(1)—the articles were drugs within the meaning of such section, and while being held for sale by the defendant, were dispensed by the defendant without a prescription.

PLEA: Guilty.

DISPOSITION: 12–16–60. $325 fine and probation for 1 year.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6484. Honegar. (F.D.C. No. 44382. S. No. 91-014 P.)

QUANTITY: Unknown quantities in 1-pt. and 1-qt. btls. at Albany, N.Y.

SHIPPED: On 2-18-60 and subsequent thereto, from Greenville, N.H., by B. T. Babbitt, Inc.

LABEL IN PART: (Btl. front panel) "Pure Honey & Apple Cidar Vinegar * * * HONEGAR * * * Honegar Division, 625 Madison Ave., New York 22, N.Y."

ACCOMPANYING LABELING: Reprint reading in part "New York Herald Tribune Honegar Found Useful as Recipe Ingredient * * * See and Hear the Honegar Story in this store today"; poster reading in part "K Kress Honegar America's Newest Home Remedy Sensation"; window streamer reading in part "You read about it in Life * * * Honegar"; display poster (inside text) reading in part "Read what Life, Time, Fortune say about Honegar"; and proof of newspaper advertisement reading in part "Would you like to try this simple 'home remedy'? * * * Honegar."

RESULTS OF INVESTIGATION: The article was shipped as described above in connection with the filling of an order for 15,000 cases of 12 1-pt. bottles each, and 10,000 cases of 6 1-qt. bottles each, which had been placed for B. T. Babbitt, Inc., with the Rowse Co., of New Hampshire, Inc., Greenville, N.H., manufacturer and packer of the article.

LIBELED: 3-21-60, N. Dist. N.Y.

CHARGE: 502(b)(1)—when shipped and while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the conditions and purposes for which it was intended, namely, for the treatment of arthritis; digestive disorders; belching; vomiting and diarrhea from food poisoning; constipation; obesity; high blood pressure; chronic fatigue; headaches, including migraine headaches; all infectious diseases, including typhoid, bronchopneumonia, peritonitis, pleurisy, dysentery, fungus diseases, common cold, chicken pox, measles; all childhood diseases; heart disease; heart attacks; essential hypertension; diabetes; insomnia; sterility; difficult labor; morning sickness; nervousness; tension; irritability; itching scalp and skin; numbness; cold hands and feet; dizziness; mental retardation; tooth decay; falling hair; breaking fingernails; paranasal sinusitis; seepage from sinuses; asthma; hay fever; facial neuralgia; retarded growth; pyelitis; thickened blood; ringing in ears; impaired hearing; Menieres syndrome; callouses and corns; slow healing of cuts and bruises; pimples; tic; cramps in muscles; blocked and swollen lymph glands; coughs; infant colic; bed-wetting; hangovers; alcoholism; and to provide vigor; promote longevity; maintain good health from the cradle to the grave; to control and reduce weight without restrictions of diet; and to reduce or eliminate the difficulties of old age.

DISPOSITION: On 5-10-60, B. T. Babbitt, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the article was ordered released under bond to be brought into compliance with the law. The claimant subsequently submitted relabeling proposals to the Food and Drug Administration. Such proposals were rejected on 8-18-60, and there-

*See also No. 6483.

after, upon motion of the claimant to determine the legality of the proposed relabeling, the matter came on for hearing before the court. On 11–22–60, the court handed down the following decision:

BRENNAN, *District Judge:* "In the present phase of this proceeding, the claimant seeks the determination of this court that its proposed action in relabeling a condemned article constitutes a compliance with the provisions of the Federal Food, Drug and Cosmetic Act (21 U.S.C.A. 301–392). The problem is pointed up by a brief background of procedure and facts set out below.

"On March 21, 1960, the United States Attorney filed a libel which prayed for the seizure and condemnation of a food article known as 'Honegar.' The United States Marshal thereafter seized 5,247 cases of bottles labeled with the trade name above and same are now the subject of this proceeding. The libel in effect charged that the seized items were in violation of the provisions of the above mentioned Act in that same, considered as a drug, were misbranded. The particular provisions of the statute involved were 21 U.S.C.A. 352(b)(1), in that the label failed to bear the name and place of business of the manufacturer, packer or distributor and 352(f)(1) in that the label thereon failed to bear adequate directions for the use for which it was intended. B. T. Babbitt, Inc., filed a claim as the owner of the seized product and filed an answer denying the essential allegations of the libel. Thereafter, upon the return day of the monition, claimant appeared and consented that a decree be entered condemning the articles seized and requested that same be returned to the claimant to be brought into compliance according to the provisions of 21 U.S.C.A. 334(d). The United States opposed the release of said article and the court exercised its discretionary power in affording such relief. An order was thereupon entered containing the usual provisions requiring that a bond be filed by the claimant and that compliance should be under the supervision of the Food and Drug Administration. It was further provided 'in the event relabeling cannot be agreed upon, and nothing in this order shall preclude the United States, from presenting proof, if any it has, that the background and past sales program make it impossible to bring it into compliance, as a food, with the Federal Food, Drug and Cosmetic Act.'

"The claimant then proceeded to negotiate with the Food and Drug Administration as to steps to be taken to place the product in compliance with the law. These negotiations culminated in a letter by claimant to the Administration dated June 29, 1960 wherein the claimant agreed to completely relabel each of the bottles, copies of the new labels being submitted with the letter. All advertising and promotional literature, seized by the Marshal, was to be destroyed and no future reference would be made to the book 'Folk Medicine' by Dr. Jarvis. The product was to be promoted and sold as a food product with no claim of therapeutic value. Same was to be marketed through claimant's sales force, food programs and food wholesalers. On August 18, 1960, claimant's proposal, as outlined above, was rejected by letter signed by the Commissioner of Food and Drugs. The bases of the rejections appear to be that the product was so connected with the contents of Dr. Jarvis' book, above mentioned, and the previous sales had been so advertised as to impress upon the public that claim was made that the product had therapeutic values to the extent that same could not be eliminated by the procedures proposed by the claimant. It was also urged that the Commissioner had determined that the product could not be successfully marketed limited as a food product. A hearing was held and evidence taken.

"Brief reference should be made to the factual background which preceded claimant's attempt to market the product in question. It seems that the medicinal qualities of honey and vinegar were advanced and discussed in a book entitled 'Folk Medicine' by Dr. Jarvis. This book was widely circulated and the offering of the product for sale by the claimant in its advertising and promotional literature leaned upon the statements contained therein. In effect, administrative determination rests upon the conclusion that the marketing of the product, through its advertising as a drug, constituted a fraud upon the public and that claimant's belated attempts to market same only as a food product are tainted with its past history.

"There is little judicial precedent to guide the court in the matter of the decision required here. Without doubt the release of the product to the claimant for the purpose of bringing same into compliance with the Act is a matter of judicial discretion. Here was a perfectly good food product, without harm in itself or to its users, condemned essentially because of the advertising and promotional material used in connection with its sale. The discretion of the court was exercised in the light of the purpose of the Act together with the principle that forfeitures are not favored.

"While the decision of the administrative body deserves respect, the decision in *Buticaps Inc.* v. *U.S.*, 252 F. 2d 634 indicates that the ultimate judgment of the sufficiency of relabeling is the obligation of the court.

> But the terms and conditions are to be fixed by the Court and not by the Department of Health, Education & Welfare. Libelee is entitled to judicial due process. (*Buticaps* v. *U.S.*, supra, page 636.)

"Turning now to the merits, this court finds that the item involved is a food product. It is a mixture of honey and vinegar. Its components are plainly stated upon the proposed labels. The claimant has never been involved in previous similar law violations. Its good faith is not questioned. The libelant's contention that the article cannot be successfully sold as a food is an economic problem, the burden of which rests upon the claimant rather than upon the United States or the court. A similar product is presently marketed by at least two companies. That a segment of the public is impressed that a food product has certain therapeutic values is common to many food items in everyday use. The marketing of such items is within the law so long as baseless claims are eliminated therefrom.

"All of the above leads to the finding and conclusion that the steps proposed to be taken by the claimant in its letter of June 29, 1960, together with the amendment which strikes the words 'Fareham Farms' from the label and substitutes the words 'Sweet 'n Sour' brings the product into compliance with the law and the claimant is entitled to a judgment or order accordingly.

"The authorities cited by the United States have not been overlooked but in general they apply to the exercise of discretion in the release of a condemned product to the claimant for the purpose of bringing same into compliance with the law rather than to the question which is involved here. An order or judgment may be submitted accordingly."

In accordance with the above decision, the court entered an order on 12–22–60 directing that the article be relabeled to designate the trade name of the article as "Sweet'n Sour Honey and Vinegar," and that the original labels and all advertising and promotional material accompanying the article be destroyed.

6485. **Geriatric Formula Food Supplement.** (F.D.C. No. 44726. S. No. 23–236 R.)

QUANTITY: 14 cases each containing 24 186-tablet boxes, at Omaha, Nebr.

SHIPPED: 2–29–60 and 3–14–60, from Los Angeles, Calif., by Belco Products Corp.

LABEL IN PART: (Box) "XDR Geriatric Formula Food Supplement Plus * * * A special formula from 100% Organic or Natural Sources with the exclusive XDR Base."

ACCOMPANYING LABELING: Leaflet entitled "Here is the story of XDR."

LIBELED: 7–20–60, Dist. Nebr.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for and preventive of physical and mental tiredness and depressed conditions; lack of vigor; rundown conditions; weakened blood; lack of resistance in conditions affecting capillary integrity and intercellular cement substances; colds; lack of health and proper sex function; prolonged illness

from any cause; loss of appetite; nervousness; neuritis; loss of muscle tone; digestive upsets; diarrhea; vague aches and pains; irritability; headache; constipation; reddening of the lips; dizziness; dryness of hair or skin; insomnia; indigestion; loss of weight; weakness; swelling and redness of the tongue or inflammation of the tongue or mouth; sores about the angle of the mouth; dental caries; anemia; defective teeth and gums; sponginess of gums; pyorrhea; gum infections; local hemorrhages of the nose, mouth, gums, and about the face; pale complexion; retarded development; lowered vitality; decreased red blood cells and hemoglobin; and night blindness; 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment for and prevention of cancer, impure blood, heart disease, ulcers, and for reducing, which were the purposes for which the article was offered in oral statements made during a sales presentation on 6–1–60, by the dealer, Andy S. Hansen, at Omaha, Nebr.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 12–6–60. Consent—destruction.

6486. Fresca powder. (F.D.C. No. 44577. S. No. 36–440 R.)

QUANTITY: 67 8-oz. jars at Philadelphia, Pa.

SHIPPED: 2–29–60, from Dinuba, Calif., by The House of Fresca.

LABEL IN PART: "Fresca Powder * * * a Medicinal Powder for Feminine Hygiene containing boric acid, alum, oil of peppermint and carbolic acid, especially prepared for use as a Douche."

LIBELED: 5–17–60, E. Dist. Pa.

CHARGE: 502(a)—when shipped, the jar label contained the false and misleading representations that the article was an adequate and effective treatment for vaginal irritations, cuts, skin abrasions, insect bites, prickly heat, chafing, "other irritations of the skin," and offensive, tender, and sore feet; and also the false and misleading statements "for use as a Douche for beneficial satisfying results" and "This powder is a high quality prescription and has fittingly proven its merits," which indicated that the article was offered for disease conditions for which it was not efficacious; and 502(f)(2)—when shipped, the labeling failed to bear the required warning statement for douche preparations, namely, "Warning: Do not use more often than twice weekly unless directed by a physician."

DISPOSITION: 12–7–60. Default—destruction.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

6487. Various drugs. (Inj. No. 376.)

COMPLAINT FOR INJUNCTION FILED: 3–21–60, N. Dist. N.Y., against Rand Pharmaceutical Co., Inc., Rensselaer, N.Y.

CHARGE: The complaint alleged that the defendant was in the business of preparing, selling, and introducing and causing to be introduced and delivering and causing to be delivered for introduction into interstate commerce, drugs which were adulterated and misbranded as follows: 501(b)—the articles purported to be drugs, the names of which were recognized in an official compendium, namely, the United States Pharmacopeia, and their strength

differed from the standards set forth in such compendium; 501(c)—they were not subject to the provisions of 501(b) and their strength differed from, and their quality feel below, that which they purported and were represented to possess; 502(a)—the labeling of the articles contained false and misleading statements with respect to the nature and quantity of the ingredients contained in the articles.

The complaint alleged also that the adulterated and misbranded condition of the drugs resulted from deficiencies in their ingredients which were due to inadequate manufacturing facilities, lack of identification control, lack of adequate analysis and formulas, or lack of other precautions essential to the preparation of drugs.

DISPOSITION: On 3–21–60, a consent decree of permanent injunction was filed. The injunction enjoined and restrained the defendants from directly or indirectly introducing or causing to be introduced, or delivering or causing to be delivered for introduction into interstate commerce, any articles of drug that are adulterated:

(a) In that their strength differs from, or their quality or purity falls below, the standard set forth in an official compendium; or

(b) In that their strength differs from, or their quality falls below, that which they purport and are represented to possess; and that are misbranded:

(a) Because of false and misleading statements in their labeling with respect to the nature and quantity of the ingredients contained therein.

The injunction further enjoined the defendant from directly or indirectly introducing or causing to be introduced or delivering or causing to be delivered for introduction into interstate commerce, any drug manufactured, prepared, relabeled or repacked by them unless and until:

(a) Sufficient qualified and experienced personnel, including supervisory personnel are employed in the defendant's plant to properly operate it;

(b) A properly qualified pharmaceutical chemist is employed to make sufficient analyses of each batch of finished drug to insure that it conforms to the labeling under which it is to be shipped and to the requirements of the National Formulary or United States Pharmacopeia or other standard which may be applicable. Lacking this, a representative sample of each finished batch of drugs is submitted to a reliable established outside laboratory for examination and the results of such examination are received prior to shipment;

(c) A system of properly identifying and storing raw materials as they are received at the plant is instituted;

(d) Batches of drugs in preparation are not manipulated in an improper manner resulting in unwarranted shortages or averages in the final yield;

(e) Sampling of finished tablets, and all other finished products is done in a representative manner to insure the taking of a representative, adequate sample;

(f) Capsules are assayed in finished form rather than in earlier stages of manufacture;

(g) Finished batches of drugs are analyzed prior to shipment;

(h) Effective new drug applications are obtained for new drugs prior to their distribution;

(i) At least one qualified person in the plant has sufficient information concerning the new drugs shipped from the plant to eliminate confusion and violations;

(j) Adequate samples of incoming raw materials are taken and appropriate analyses of these samples made;

(k) Preparation of manufacturing records and forms is done with such clarity, care and completeness so that each lot or batch of drugs manufactured, prepared, relabeled, or repacked is so identified that the complete manufacturing, packing, and labeling history and control examination reports are readily available and so as to eliminate mistakes and confusion;

(l) Each batch or lot of drugs manufactured, prepared, relabeled or repacked is properly identified at all times and during all stages of said manufacturing, preparation, relabeling or repacking;

(m) Operations involving the weighing out of raw materials and the preparation of formulas and application of labeling are checked by another qualified party in addition to the employee originally performing such duties;

(n) Returned goods are recorded, handled, stored, and again disposed of in a manner which will eliminate uncertainty, confusion and the possibility of mistakes;

(o) Samples of each lot of raw materials and each batch or lot of drugs manufactured, prepared, relabeled or repacked by them are taken and retained for the time reasonably necessary for the distribution and use of drugs distributed;

(p) Representatives of the Food and Drug Administration of the Department of Health, Education, and Welfare are given free access to all records and controls pertaining to (1) the receipt of all raw materials or lots of drugs for manufacturing, preparing, repacking or relabeling; (2) the manufacturing, preparing, repacking or relabeling of all lots or batches of drugs; and (3) the distribution of all batches or lots of drugs whether interstate or intrastate, including, but not limited to, the records necessary to establish that adequate control systems have been installed embodying all of the herein listed safeguards for interstate commerce considered necessary to good pharmaceutical manufacturing practice.

6488. Procaine penicillin G in streptomycin sulfate in aqueous suspension. (F.D.C. No. 44851. S. No. 34–825 R.)

QUANTITY: 2,942 vials at New York, N.Y.

SHIPPED: On 3–31–60, from New York, N.Y., to Phoenix, Ariz., and returned to New York on 6–9–60.

LABEL IN PART: "10 cc. size 5 doses Procaine Penicillin G in Streptomycin Sulfate in Aqueous Suspension."

RESULTS OF INVESTIGATION: Examination showed that the article was badly discolored and lumpy; that it could not with certainty be uniformly resuspended; that withdrawal with a 22-gauge needle was nearly impossible; and that the article contained substantially less than its labeled content of penicillin and streptomycin.

LIBELED: On or about 8–19–60, S. Dist. N.Y.

CHARGE: 501(c)—while held for sale, the strength of the article differed from and its purity and quality fell below that which it purported and was represented to possess, since *procaine penicillin G in streptomycin sulfate in aqueous suspension* is recognized in the Antibiotic Regulations (21 CFR 146a.67) and it failed to conform to the standard set forth in such regulations since it did not contain the potency represented and it was not in an aqueous

suspension which, upon being shaken a reasonable length of time, would insure a uniform distribution of solid in vehicle and, therefore, uniform and proper dosage.

DISPOSITION: 9–20–60. Default—destruction.

6489. Sodium para-aminosalicylic acid tablets. (F.D.C. No. 43394. S. No. 61–104 P.)

QUANTITY: 74 24-btl. cartons and 25 btls. at Detroit, Mich.

SHIPPED: Between 5–22–59 and 6–4–59, from Auburn, Mass., by Cowley Pharmaceuticals, Inc.

LABEL IN PART: "1,000 Tablets Salamin Sodium Each Tablet Contains: Sodium Para-Aminosalicylic Acid 0.5 grams (7.72 grains)."

RESULTS OF INVESTIGATION: Examination showed that the article contained 87.6 percent of the labeled amount of sodium para-aminosalicylic acid; that the average weight of tablets in two subdivisions was below declared weight of active ingredient; and that a substantial number of broken tablets were found in the sample. United States Pharmacopeia requires *sodium para-aminosalicylic acid tablets* to contain from 95 to 105 percent of labeled amount of the drug.

LIBELED: 7–22–59, E. Dist. Mich.

CHARGE: 501(b)—when shipped, the article purported to be a drug recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below the standard set forth in the compendium; 502(a)—the label statement "Each tablet contains: Sodium Para-Aminosalicylic Acid 0.5 grams (7.72 grains)" was false and misleading.

DISPOSITION: 12–28–60. Consent—claimed by shipper and reconditioned to be brought into compliance with the law.

6490. Posterior pituitary injection. (F.D.C. No. 45135. S. No. 41–134 R.)

QUANTITY: 12 vials at St. Louis, Mo.

SHIPPED: 8–22–60, from Chicago, Ill., by Medical Chemicals Corp.

LABEL IN PART: (Vial) "10 cc Sterile Multiple Dose Vial Posterior Pituitary Injection 10 U. S. P. Units/cc (Obstetrical) 0.5 Chlorobutanol * * * Medical Chem. Corp. Chicago 51, Ill. 6132."

RESULTS OF INVESTIGATION: Analysis showed that the potency of the article was not more than 4.6. U. S. P. posterior pituitary units per cubic centimeter.

LIBELED: 11–7–60, E. Dist. Mo.

CHARGE: 501(b)—when shipped, the strength of the article fell below the standard set forth in the United States Pharmacopeia; and 502(a)—the label statement "Posterior Pituitary Injection 10 U. S. P. Units/cc" was false and misleading.

DISPOSITION: 12–14–60. Default—destruction.

6491. Rubber prophylactics. (F.D.C. No. 44536. S. No. 32–793/5 R.)

QUANTITY: 56 ctns., each containing 48 3-unit paper sleeves; 138 ctns., each containing 48 3-unit plastic cans; 198 ctns., each containing 12 paper sleeves of 4 3-unit paper packs, at Brooklyn, N.Y.

SHIPPED: 2–16–60 and 3–18–60, from Akron, Ohio, by March Rubber & Plastic Co.

LABEL IN PART: (Ctn. and sleeve of 56-ctn. lot) "Gladiator 3 pack reservoir end * * * Prophylactics"; (can of 138-ctn. lot) "Sold for the prevention of disease only Gladiator transparent thins"; and (ctn. and sleeve of 198-ctn. lot) "Checks Deluxe Thin Prophylactics."

RESULTS OF INVESTIGATION: Examination revealed that 3 out of 96 units of the article in the 56-ctn. lot, 3 out of 144 units of the article in the 138-ctn. lot, and 3 out of 150 units of the article in the 198-ctn. lot contained holes.

LIBELED: 4–29–60, E. Dist. N.Y.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess; 502(a)—the label statements "Prophylactics" (56-ctn. and 198-ctn. lots) and "Sold for the prevention of disease only" (138-ctn. lot) were false and misleading as applied to a product which contained holes.

DISPOSITION: 6–23–60. Consent—claimed by the shipper and destroyed.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

6492. Safflower seed oil, soy oil, vitamin B_2 tablets, vitamin A capsules, V-Complete multivitamin and mineral tablets, Super Potency multivitamin and mineral tablets, Liverall tablets, vitamin C, vitamin B complex tablets, brewer's yeast powder and tablets, wheat germ cereal, flaked yeast, sunflower seeds. (F.D.C. No. 45016. S. Nos. 8–481/3 R, 8–485/95 R.)

QUANTITY: 1 150-lb. drum, and 3 qt. btls., 21 pt. btls., and 3 gal. containers, of safflower seed oil; 50 qt. btls., 57 pt. btls., and 6 gal. btls., of soy oil; 17 100-tablet btls. of vitamin B_2; 1 100-capsule btl., and 5 250-capsule btls. of vitamin A; 4 300-tablet btls., 6 100-tablet btls., and 7 60-tablet btls., of V-Complete multivitamins and minerals; 11 300-tablet btls., 2 100-tablet btls., and 6 60-tablet btls., of Liverall; 4 4-lb. jars, and 11 1-lb. jars, of brewer's yeast; 11 1,000-tablet btls. of brewer's yeast; 47 100-tablet btls. of Super Potency multivitamin and minerals; 22 100/100 mg. btls., 15 250/100 mg. btls., 5 500/100 mg. btls., 1 250/200 mg. btl., and 5 500/250 mg. btls., of vitamin C; 3 100-tablet btls., 17 250-tablet btls., and 6 500-tablet btls., of vitamin B complex; 5 ctns., 12 9-oz. pkgs. each, of wheat germ cereal; 148 1-lb. bags of flaked yeast; and 120 12-oz. jars, 134 1-lb. packs, and 4 50-lb. bags, of sunflower seeds, at Rochester, N.Y., in possession of Niblack Foods, operating a retail outlet under the name of Dietary Specialties.

SHIPPED: Between the approximate dates of 12–31–58 and 8–3–60, from various places outside the State of New York.

LABEL IN PART: (Btls.) "Niblack's Safflower Seed Oil 92% Unsaturated Fatty Acids Contents * * * Packed by Niblack Foods, Rochester 8, N.Y.," "Niblack's Soy Oil Contents * * * Niblack Foods, Rochester 8, N.Y.," "Thompson's Standardized Vitamins Vitamin B_2 10 Milligrams HH 2579 Each tablet contains 10 Milligrams of Riboflavin (Vitamin B_2)," "Thompson's Standardized Vitamins Vitamin A 20,000 U.S.P. Units Per Tablet #1332S," "V-Complete Natural Vitamins Natural Minerals Organic Iron+B_{12} * * * A Food Supplement Providing an Excellent Source of Food Derived Vitamins and Minerals Skillfully Combined with an Organic Iron Compound," and "Schiff Natural Liverall Desiccated Low Heat Dried Liver"; (jar) "Schiff

*See also Nos. 6485–6487, 6489–6491.

Brewer's Yeast U.S.P. Fortified with A.P.F. Vitamin B-12 Natural B Complex Protein"; (btls.) "Brewer's Yeast U.S.P. Grade A good source of protein (50%) and vitamin B Complex natural to non-fermenting U.S.P. Dried Brewer's Yeast," "Super Potency Natural & Organic Vitamins and Minerals A Natural Food Supplement with Vitamin B-12 and Organic Iron. * * * Distributed by Niblack Foods, 20 Magnolia Street, Rochester 8, New York 42679," Thompson's Standardized Vitamins Vitamin C * * * 2,000 U.S.P. Units Each," and "Thompson's Standardized Vitamins Vitamin B Complex Special High Potency All Important B-Complex Vitamins in a Natural Base"; (pkg.) "Battle Creek Protein–Rich . . . Ready to Eat! Wheat Germ Plus Other Parts of Wheat Flakes A Delicious New Hi-Nourishment Cereal! Ingredients—Wheat Germ, Other Parts of Wheat, Sugar Molasses and Salt"; (bag) "Flaked Yeast 1 Lb."; and (jar) "Niblack's Vacuum Packed Hulled Sunflower Seeds Raw Packed by Niblack Foods, Rochester 8, New York."

ACCOMPANYING LABELING: Reprints of the following articles from "Health Saver National Consumer Health Food Magazine," all by Roland Evin Horvath, Editor: "Cancer in Your Foods," "How to Protect Your Heart," "Don't Let Headaches Afflict You!," "End Your Sinus Trouble!," "Healthy Eyesight and Vitamins," and "Key to Vibrant Health Sunflower Seeds."

RESULTS OF INVESTIGATION: The above-mentioned *safflower seed oil* in the quart and pint bottles and in the gallon containers, the *soy oil*, the *Super Potency multivitamin and mineral tablets*, the *flaked yeast*, and the *sunflower seeds*, were repacked by the dealer from bulk lots shipped as described above.

LIBELED: 10–19–60, W. Dist. N.Y.

CHARGE: *Safflower seed oil* and *soy oil*. 502(a)—while held for sale, the accompanying labeling of the articles, consisting of the reprint entitled "How to Protect Your Heart," contained false and misleading representations that the articles were adequate and effective as a treatment to prevent heart disease, cholesterol deposits in the arteries, heart attack, cerebral hemorrhage, clogged arteries, angina pectoris, and arteriosclerosis.

Vitamin B_2 tablets. 502(a)—while held for sale, the accompanying labeling of the article, consisting of the reprint entitled "Healthy Eyesight and Vitamins," contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of bloodshot eyes; dimming vision; burning eyeballs; eye weakness and excessive watering; cataracts; premature aging; dark, lumpy pouches around eyes; spots before eyes; eye aches; extreme sensitivity to ordinary light; sandlike roughness beneath eyelids; eyestrain causing headaches, nervousness, general fatigue, faulty digestion, sleeplessness, inability to concentrate, general inefficiency; and to prevent serious eye infections.

Vitamin A tablets. 502(a)—while held for sale, the accompanying labeling of the article, consisting of reprints entitled "End Your Sinus Trouble" and "Healthy Eyesight and Vitamins," contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of sinus trouble; bloodshot eyes; dimming vision; burning eyeballs; eye weakness and excessive watering; cataracts; premature aging; dark, lumpy pouches under eyes; spots before eyes; eye aches; eye strain causing headaches, nervousness, general fatigue, faulty digestion, sleepless-

ness, inability to concentrate, and general inefficiency; harmful consequences to the eyes due to viewing television; and to keep eyes normal, healthy, and sparkling.

V-Complete multivitamin and mineral tablets and *Super Potency multivitamin and mineral tablets.* 502(a)—while held for sale, the accompanying labeling of the articles, consisting of the reprint entitled "How to Protect Your Heart," contained false and misleading representations that the articles were adequate and effective as a treatment for and preventive of heart disease, atherosclerosis, heart attack, cerebral hemmorrhage, clogged arteries, angina pectoris, and arteriosclerosis.

Liverall tablets. 502(a)—while held for sale, the accompanying labeling of the article, consisting of the reprint entitled "Cancer in Your Foods," contained false and misleading representations that the article was adequate and effective as a preventive of cancer; that vitamin B_{12} and folic acid have a protective effect on the liver and speed recovery from viral hepatitis (liver infection); that kelp and honey are adequate and effective as a treatment for and preventive of muscle weakness, diminished tendon reflexes, serious electrocardiogram changes; and that liver cancer occurrence is associated with the lack of adequate proteins and vitamins and cirrhosis of the liver.

Vitamin C tablets. 502(a)—while held for sale, the accompanying labeling of the article, consisting of reprints entitled "Cancer in Your Foods" and "End Your Sinus Trouble," contained false and misleading representations that the article was adequate and effective as a preventive of cancer; as a treatment for and preventive of sinus trouble, aches and pains of sinus infection, and to build resistance to bacterial invasions which result in sinus trouble; that vitamin B_{12} and folic acid have a protective effect on the liver and speed recovery from viral hepatitis (liver infection); that kelp and honey are adequate and effective as a treatment for and preventive of muscle weakness, diminished tendon reflexes, serious electrocardiogram changes; and that liver cancer occurrence is associated with the lack of adequate proteins and vitamins and cirrhosis of the liver.

Vitamin B complex tablets. 502(a)—while held for sale, the accompanying labeling of the article, consisting of reprints entitled "Cancer in Your Foods," "How to Protect Your Heart," and "Don't Let Headaches Afflict You!," contained false and misleading representations that the article was adequate and effective as a preventive of cancer; as a treatment for and preventive of heart disease, atherosclerosis, heart attack, and cerebral hemorrhage, headaches, jangled nerves, irritability, nervousness, fatigue, feeling of depression, muscle and joint pains, lassitude, inefficiency, emotional stress and strain, poor appetite, irregular bowel movements to severe constipation, quarrelsomeness, and jumpiness; that vitamin B_{12} and folic acid have a protective effect on the liver and speed recovery from viral hepatitis (liver infection); that kelp and honey, in view of their content of potassium, are adequate and effective as a treatment for and preventive of muscle weakness, diminished tendon reflexes, serious electrocardiogram changes; and that liver cancer occurrence is associated with the lack of adequate proteins and vitamins and cirrhosis of the liver.

Brewer's yeast powder and tablets. 502(a)—while held for sale, and accompanying labeling of the articles, consisting of reprints entitled "Cancer in Your Foods" and "Don't Let Headaches Afflict You!," contained false and misleading representations that the articles were adequate and effective as a preventive of cancer; as a treatment for and preventive of headaches, jangled

nerves, irritability, nervousness, fatigue, feeling of depression, muscle and joint pains, lassitude, inefficiency, emotional stress and strain, poor appetite, irregular bowel movements to severe constipation, quarrelsomeness, and jumpiness; that vitamin B_{12} and folic acid have a protective effect on the liver and speed recovery from viral hepatitis (liver infection); that kelp and honey are adequate and effective as a treatment for and preventive of muscle weakness, diminished tendon reflexes, serious electrocardiogram changes; and that liver cancer occurrence is associated with the lack of adequate proteins and vitamins and cirrhosis of the liver.

Wheat germ cereal. 502(a)—while held for sale, the accompanying labeling of the article, consisting of the reprint entitled "Cancer in Your Foods," contained false and misleading representations that the article was adequate and effective as a preventive of cancer; that vitamin B_{12} and folic acid have a protective effect on the liver and speed recovery from viral hepatitis (liver infection); that kelp and honey are adequate and effective as a treatment for and preventive of muscle weakness, diminished tendon reflexes, serious electrocardiogram changes; and that liver cancer occurrence is associated with the lack of adequate proteins and vitamins and cirrhosis of the liver.

Flaked yeast. 502(a)—while held for sale, the accompanying labeling of the article, consisting of reprints entitled "Cancer in Your Foods" and "Don't Let Headaches Afflict You!," contained false and misleading representations that the article was adequate and effective as a preventive of cancer; and as a treatment for and preventive of headaches, jangled nerves, irritability, nervousness, fatigue, feeling of depression, muscle and joint pains, lassitude, inefficiency, emotional stress and strain, poor appetite, irregular bowel movements to severe constipation, quarrelsomeness, and jumpiness; that vitamin B_{12} and folic acid have a protective effect on the liver and speed recovery from viral hepatitis (liver infection); that kelp and honey are adequate and effective as a treatment for and preventive of muscle weakness, diminished tendon reflexes, serious electrocardiogram changes; and that liver cancer occurrence is associated with the lack of adequate proteins and vitamins and cirrhosis of the liver.

Sunflower seeds. 502(a)—while held for sale, the accompanying labeling of the article, consisting of the reprint entitled "Key to Vibrant Health Sunflower Seeds," contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of pellagra, improper skin, digestive, and nervous systems, heart conditions, heart trouble, heart attack, atherosclerosis, to control and reduce the cholesterol level of the blood, prevent sterility, reduce and eliminate body wastes, and build sound bones and teeth, activate and regulate enzymes, for proper fat and carbohydrate digestion, to build good muscle and tissue tone, promote proper nerves and clotting of blood, healthy, red blood corpuscles, hard tooth enamel, maintain the natural fluidity of the blood, promote normal growth and metabolism, appetite, proper nerve functioning, good mobility and tone of stomach and intestines, proper digestion, healthy skin, and increase endurance.

The libel alleged also that the *flaked yeast* and the *sunflower seeds* were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 12–5–60. Consent—claimed by Everett J. Niblack, t/a Dietary Specialties, and relabeled.

6493. Vitamin preparations. (F.D.C. No. 45106. S. Nos. 53–221/7 R.)

QUANTITY: Various quantities of *Vigran Multi-Vitamins* in bottles of 30 or 100 capsules, *Vigran M Vitamin-Minerals* in bottles of 30 or 100 tablets, *Theragran Squibb Therapeutic Formula vitamin capsules* in bottles of 30 or 100 capsules, *Novogran Squibb Stress Formula Water Soluble Vitamins* in bottles of 100 capsules, *Theragran M Squibb Vitamin-Minerals for Therapy* in bottles of 100 tablets, *Theragran Liquid 4 fl. oz. Squibb Therapeutic Formula Vitamin Liquid*, and *Theragran Junior Squibb Vitamins for Therapy* in bottles of 100 capsules, at Cambridge, Mass.

SHIPPED: On various dates prior to 11–8–60, from Brooklyn, N.Y., by E. R. Squibb & Sons, Div. of Olin Mathieson Chemical Corp.

ACCOMPANYING LABELING: Booklets entitled "Selling Slants on Vitamins" and "Vitamins and Your Sales Success"; envelope entitled "Questions on the Squibb Vitamin Instruction Course," which contained separate sheets headed "Questions–Lesson No. I [or "II," "III," "IV," "V," and "VI"] leaflets entitled "All Vitamins are not alike!" and "Take Vitamins in the Summertime?"; and window-streamers headed "V for Vigran Multi-Vitamins Ask Us About the Vigran Vitality Program."

LIBELED: 11–22–60, Dist. Mass.

CHARGE: All articles, 502(a)—when shipped, the above-mentioned booklets contained false and misleading representations that additional quantities of vitamins, far in excess of the amount recommended for adequate nutrition, would provide additional benefits for persons in good health, and would assist in returning a sick or injured person, or one convalescing from an operation, to good health, that the body has a greatly increased need for vitamin supplementation during and after stress conditions such as major surgery, severe burns, fractures, and severe and prolonged illnesses, which increased need is an indication for the use of the excess quantities of vitamins offered by the articles; 502(a)—the above-mentioned booklets contained statements which represented and suggested that the articles were offered for the treatment and prevention of night blindness; loss of appetite; fatigue; insomnia; irritability; heart and circulatory disturbances; digestive disturbances; faulty elimination; weight loss; neuritic pain; aches and pains; headaches; colds; general run-down condition; gastrointestinal disorders; mental and physical inadequacy; beriberi; mouth irritation; dry scaling of the red surface of the lips and corners of the mouth; photophobia; loss of appetite; nervousness; mental depression; soreness and redness of the tongue; ulceration of the gums; anemias; diarrhea; pellagra; skin disorders, with the malignant malnutrition of the tropics; emaciation; weakness and stupor; diseases of the gums; scurvy; redness, bleeding, and receding of gums; and multiple hemorrhages into the skin, joints, muscles, and internal organs; which statements were false and misleading since the articles were not an adequate and effective treatment and preventive of such diseases, conditions, and purposes; 502(a)—the above-mentioned booklets also contained statements which suggested that pernicious anemia results from a dietary deficiency of vitamin B_{12}, which would be corrected by supplementation of the diet with that vitamin, which statements were false and misleading since lack of intrinsic factor is a result of failure of the function of the body to produce that factor, leading to the disease, pernicious anemia, which disease is not amenable to treatment or correction, nor can the intrinsic factor be replaced, by use of the vitamin supplements offered.

The articles were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 4–27–61. Consent—claimed by Olin Mathieson Chemical Corp., and relabeled.

6494. Omin Plus iron phosphate tablets. (F.D.C. No. 44210. S. Nos 85–709/11 P.)

QUANTITY: 6 tins of Lot No. 41701, 7 tins of Lot No. 41702, and 4 tins of Lot No. 41703, each tin containing 25,000 tablets, at Fishkill, N.Y., in possession of Omin Co., Inc.

SHIPPED: Between 2–11–59 and 2–16–59, from Worcester, Mass.

LABEL IN PART: "Private Formula * * * Omin-Plus * * * Iron (Ferric) Phosphate 67 mg. (160% MDR)."

ACCOMPANYING LABELING: Streamers entitled "How Red Is Your Blood * * * Omin Plus," "Tired? Got That Worn-Out Feeling * * * Take Omin Plus," "Tired? Worn-Out? * * * Omin Tablets"; circular entitled "Omin Vitamins Omin Plus"; and charts entitled "Human Factory."

RESULTS OF INVESTIGATION: Analyses showed that the article contained approximately (Lot No. 41701) 55 percent, (Lot No. 41702) 58 percent, and (Lot No. 41703) 55 percent of the declared amounts of iron.

LIBELED: 2–11–60, S. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the accompanying streamers, circulars, and charts contained false and misleading representations that the article was adequate and effective for the prevention and treatment of that tired, worn-out feeling; would restore pep and energy and make one feel better; would produce an adequate supply of red, healthy blood; that the article contained properties necessary to control and maintain proper glandular secretions and chemical functions of the human body; and that the article would serve to control and maintain proper functions of all glands and other organs and the metabolic processes of the human body to enjoy health.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 7–29–60. Default—destruction.

6495. Vitamin D in a soybean oil base. (F.D.C. No. 44191. S. No. 76–777 P.)

QUANTITY: 3,760 100-capsule btls. and 338 500-capsule btls. at Portland, Oreg., in the possession of Fred Meyer, Inc.

SHIPPED: Between 8–21–59 and 10–15–59, from Santa Monica and South Pasadena, Calif., and Newark, N.J.

LABEL IN PART: (Btl.) "Certified Capsules Lecithin with Vitamin D Dosage * * * Distributed by Fred Meyer, Inc., Portland, Oreg. Each Capsule Contains: Soy Lecithin 259.2 mg. Soy Bean Oil 170.2 mg. Vitamin D 150 USP Units (Irradiated Ergosterol)."

ACCOMPANYING LABELING: Placards entitled "Stay Alive Longer! Lecithin" and newspaper clippings of advertisements placed in a Portland newspaper by Fred Meyer, Inc., reading in part "Lecithin As Advised by Lelord Kordel," and "Stay Alive Longer Lecithin."

RESULTS OF INVESTIGATION: Investigation indicated that the product was vitamin D in a soybean oil base. The article was shipped in bulk as described above, and after arrival at Portland, Oreg., was repacked and labeled by the Stanley Drug Products, Inc., and then delivered to Fred Meyer, Inc.

LIBELED: 1–20–60, Dist. Oreg.; amended libel 8–11–60.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the prevention of fatigue, irritability, brain fag, and nervous exhaustion; that it nourished brain cells and supplied motive force; that it would restore depleted brain power and waning activity of vital organs; and that it would prevent globules from settling on the artery walls or infiltrating the liver; 502(a)—the term "Lecithin" in the labeling designated for this article—e.g. "STAY ALIVE LONGER! LECITHIN * * * As Advised by LELORD KORDEL," created a false and misleading impression in the minds of prospective purchasers since the term "Lecithin" as used in the promotion of the article was thereby associated with false and misleading information disseminated to the public in a book and a series of newspaper articles by said Lelord Kordel entitled "Stay Alive Longer," which appeared in a Portland newspaper commencing October 22, 1959, to the effect that lecithin-containing capsules are effective in the treatment and prevention of atherosclerosis; pale and drawn face; nervousness; weak, jangly nervous system; insomnia; irritability; nervous, mental, and glandular overactivity; exhaustion; loss of vitality; loss of cerebrospinal fluid; nerve and gland exhaustion; nervous breakdown; headaches; brain fag; senility; tension; shattered nerves; depleted brain power; waning activity of vital glands; depletion of fatty myelin sheath of nerves; sexual decline; and fat infiltration of the liver and other organs; and would create a strong nervous system, endocrine glands, muscles of the heart and kidneys; would neutralize body poisons of internal and external origin; would prevent fat from settling on artery walls; and would restore life forces; and 502(a)—the name of the article and the label declaration of amounts of soy lecithin and soybean oil in the article were misleading in that they represented and suggested that these ingredients were present in therapeutically significant quantities whereas the lecithin and soybean oil in the article were therapeutically insignificant.

DISPOSITION: 11–18–60. Fred Meyer, Inc., claimant, having consented to the entry of a decree without admitting the allegations of misbranding, judgment of condemnation was entered and the article was released under bond for relabeling.

6496. Vitamin products. (F.D.C. No. 44902. S. Nos. 41–771 R, 42–301 R, 42–308 R, 42–310/3 R, 42–315/6 R, 42–318 R, 42–320 R.)

QUANTITY: 2 cases of 96 160-tablet btls. of *yeast and iron tablets;* 4 cases of 96 200-tablet btls. of *Multi-Mineral tablets;* 6 cases of 96 200-tablet btls. and 3 cases of 96 100-tablet btls. of *vitamin A and D tablets;* 1 case of 168 50-capsule btls. of *vitamin A, B_1, D, G capsules;* 4 cases of 96 100-tablet btls. of *vitamin B complex tablets;* 5 cases of 6 600-tablet btls. of *vitamin A and D and B_{12} tablets;* 4 cases of 96 120-capsule btls. of *Junior Multi-Vitamins-Mineral capsules;* 3 cases of 108 45-capsule btls. of *Geratric Multi-Vitamins-Mineral capsules;* 34 cases of 12 8-oz. btls. of *liquid vitamin for infants and children;* and 4 cases of 144 60-tablet btls. of *cold tablets with vitamin C,* at Oakland, Calif.

SHIPPED: Between 7–31–57 and 7–15–60, from Freeport, Ill., by W. T. Rawleigh Co.

LABEL IN PART: (Btl.) "Rawleigh's Yeast and Iron Tablets"; "Rawleigh's Multi-Mineral Tablets"; "Rawleigh's Vitamin A and D Tablets"; "Rawleigh's Vitamins A, B_1, D, G"; "Rawleigh Vitamin B-Complex Tablets"; "Rawleigh's

Vitamin A and D and B-12 Tablets"; "Rawleigh's Junior Multi-Vitamin-Mineral Capsules For Children 3 to 12 Years of Age"; "Rawleigh's Geriatric Multi-Vitamin-Mineral Capsules"; "Rawleigh Liquid Vitamin for Infants and Children"; and "Rawleigh's Cold Tablets with Vitamin C."

ACCOMPANYING LABELING: Booklets entitled "Rawleigh and today's homemaker" and "Pocket Reference Booklet on Rawleigh Products"; leaflets entitled "Better Health more vigor and zest for life," "Who needs vitamin supplements," and "To help babies and children grow and be healthy"; and looseleaf books entitled "Rawleigh's Sales Manuals."

LIBELED: 9–22–60, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling of the *Multi-Mineral tablets* contained false and misleading representations that the article was adequate and effective to prevent subnormal conditions and severe ailments, and to promote growth and health;

502(a)—the label of the *vitamin A and D tablets* bore the false and misleading statement "to prevent and overcome soft bones in infants and early childhood," and the article's labeling contained false and misleading representations that the article was adequate and effective to promote sturdy bones and teeth, healthy mucous membranes, skin and eyes of people of all ages, good appetite, proper intestinal activity, sound nerves, and sense of well-being, strong, well-shaped bones and teeth, and to increase the life span of adults;

502(a)—the labeling of the *vitamin B complex tablets* contained false and misleading representations that the article was adequate and effective for the treatment and prevention of insomnia; mental depression; depressed, restless feelings and worry; and to promote sound nerves, digestion, skin and eyes, good appetite and proper intestinal activity;

502(a)—the label of the *vitamin A and D and B_{12} tablets* bore the false and misleading statement "to prevent and overcome soft bones in infants and early childhood," and the labeling contained false and misleading representations that the article was adequate and effective to promote normal growth, sound bones and teeth, healthy appetite, resistance to infection of eyes, nose and throat; to protect eyesight from night blindness; and help thin children gain weight;

502(a)—the labeling of the *Junior Multi-Vitamin-Mineral Capsules* contained false and misleading representations that the article was adequate and effective to promote growth and health, and to keep children from losing days at school due to coughs and colds and other illnesses;

502(a)—the labeling of the *yeast and iron tablets* contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of exhaustion during hard work, nervousness, pain and weakness, neuritis, polyneuritis, progressive blindness, pellagra, and beriberi; and to promote sound nerves and sense of well-being; to increase energy, endurance, and morale; to stimulate appetite, digestion and intestinal activity and elimination; to stimulate assimilation and utilization of nutrients; develop clear skin and complexion; to maintain normal cell life and proper function of glands; and as a tonic;

502(a)—the labeling of the *vitamins A, B_1, D, G capsules* contained false and misleading representations that the article was adequate and effective to promote good appetite, intestinal activity, sound nerves and sense of well-being, strong, well-shaped bones and teeth, to keep eyes, mucous membranes and skin healthy, and to increase the life span of adults;

502(a)—the labeling of the *Geriatric Multi-Vitamin-Mineral capsules* contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of weakened capillaries and capillary breakdown, heart and blood vessels, fatty livers, depressed or unstable conditions, all-tired-out feeling, poor night vision, upset digestion, rough skin, sore itching eyes, poor teeth, weight loss, emotional instability, lack of appetite, constipation, tired eyes, headaches, sore mouth, pink eye, cataracts, lack of pep, worry, restlessness, anemia, premature aging, conditions associated with stress and strain, weakness, vague muscle aches, "spring fever," tooth decay, poor sleep, inflammation of skin, loss of hair, failure of liver function, weak bones, blood not up to par, bone deformities; and that the article would lengthen life, promote growth, power reproduction, promote general health, and proper functioning of stomach, intestines and skin, dilate arteries to promote good circulation, build protein, fight infection, and develop vigor and zest for life;

502(a)—the labeling of the *liquid vitamin for infants and children* contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of infections, overweight, slow growth, poor circulation; and that the article would keep eyes, mucous membrane, and skin healthy; promote growth in children; increase life span of adults; build strong, sturdy bones and teeth; promote good appetite and digestion, sound nerves, sense of well-being, general health, strong, tough blood vessels, normal gland functioning, height and weight in children, normal cell life and sound nerves, proper functioning of the stomach and intestines; improve the flow of blood of older persons; and promote energy;

502(a)—the labeling of the *cold tablets with vitamin C* contained false and misleading representations that the article was adequate and effective to prevent infection; increase physical endurance; lessen fatigue; secure proper functioning of blood vessels, and keep resistance to illnesses caused by infectious germs, including colds and influenza, at the highest level; and that fever and infection require extra nutritional amounts of vitamin C.

The libel alleged also that the articles, except for the *yeast and iron tablets*, the *vitamin A, B_1, D, G capsules*, and the *cold tablets with vitamin C*, were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 10–27–60. Default—delivered to county institutions for use under a physician's instruction.

6497. Spray-O-Med medicated vapor. (F.D.C. No. 44576. S. No. 34–895 R.)

QUANTITY: 259 cases, 24 3-oz. cans each, and 301 cases, 12 7-oz. cans each, at Brooklyn, N.Y.

SHIPPED: 12–2–59 and 2–16–60, from Newark, N.J., by Sun-Lac, Inc.

LABEL IN PART: (Can) "Spray-O-Med Medicated Vapor * * * Active ingredients—Menthol, Triethylene Glycol, Eucalyptol, Thymol * * * Health Specialties Division, Chemical Specialties Co. B'klyn 22, N.Y."

RESULTS OF INVESTIGATION: Examination showed the article to be packaged in aerosol-type cans which would emit a spray or vapor having a strong odor of thymol and other aromatics.

LIBELED: 5–23–60, E. Dist. N.Y.

CHARGE: 502(a)—when shipped, the can label of the article contained false and misleading representations that it was an adequate and effective treatment for relieving miseries of colds, sinus, hay fever, and other nasal allergies; clearing the head; and soothing the throat.

DISPOSITION: 8–29–60. Consent—article claimed by Harry Shapiro, t/a Chemical Specialties Co. and relabeled.

6498. **Brand Nu.** (F.D.C. No. 44910. S. Nos. 28–024 R, 28–050 R.)

QUANTITY: Unknown number of 4 gram packets and cartons, each containing 25 4-gram packets at Minneapolis, Minn., in possession of Standard Industries, Inc., and others.

SHIPPED: Prior to March 1960, from Chicago, Ill.

LABEL IN PART: (Packet) "Combats over indulgence or that 'morning after feeling.' Brand Nu * * * For best results take one before or during indulgence and one the following morning before eating."

RESULTS OF INVESTIGATION: The article had been shipped in different containers and after receipt at Minneapolis was repacked by Standard Industries, Inc.

LIBELED: 10–3–60, Dist. Minn.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that it was an adequate and effective treatment for overindulgence and that "morning after feeling."

The article was alleged also to be misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods, No. 27399.

DISPOSITION: 12–30–60. Default—destruction.

6499. **Oro-Vita food supplement.** (F.D.C. No. 44262. S. Nos. 84–053 P, 17–305 R.)

QUANTITY: 34 cases, each containing 6 ctns., each ctn. containing 360 mineral tablets and 180 vitamin tablets, at Salt Lake City, Utah, in possession of Oro-Vita Corp.; and 160 packages, each containing 2 ctns. of 360 mineral tablets and 180 vitamin tablets; 450 envelopes, each containing 4 mineral tablets and 2 vitamin tablets; 39 drums, each containing 21,239 mineral tablets and 21 drums, each containing 21,239 vitamin tablets, at Salt Lake City, Utah, in possession of "N" Products Co.

SHIPPED: 8–15–59 and 2–15–60, from Los Angeles, Calif.

LABEL IN PART: (Case) "Oro-Vita (Golden Life) Food Supplement With Special *Tramin Base Natural or Organic Minerals and Vitamins * * * The special Tramin Base contains what many believe to be a unique nutritional discovery which contains some of mother nature's blended elements from the land, from the sea and from what used to be the bottom of the sea. Among these elements are Minerals and Vitamins * * * Formulated for and Distributed by Oro-Vita Corporation, Salt Lake City, Utah"; (ctn.) "Oro-Vita Food Supplement with special *Tramin Base Natural or Organic Minerals and Vitamins * * * 360 (Brown) Mineral Tablets 180 (Yellow) Vitamin Tablets * * * Oro-Vita Corporation, Salt Lake City, Utah"; (pkg.) "Oro-Vita (Golden Life) Food Supplement With Special *Tramin Base Natural or Organic Minerals and Vitamins * * * Distributed by Oro-Vita Corporation, Salt Lake City, Utah"; and (envelope) "Oro-Vita Food Supplement 1 Day Supply."

ACCOMPANYING LABELING: Loose repack labels for packages and cartons, as described above; leaflets entitled "What Charlie Morgan Learned About

Minerals"; "Is Health Your Most Treasured Asset?"; reprints of a Reader's Digest article entitled "How To Prolong The Prime of Life"; reprints of a Pageant magazine article entitled "Vitamins Can Help You Live Longer"; and sales manuals entitled "Oro-Vita * * * Food Supplement."

RESULTS OF INVESTIGATION: The article was repacked into cases, packages, and envelopes by "N" Products Co., Salt Lake City, Utah, for Oro-Vita Corp., from the bulk containers shipped as described above.

LIBELED: 3–24–60, Dist. Utah.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was adequate and effective for the treatment and prevention of tired, sluggish, depressed conditions, nervousness, fatigue, irritability, low vitality, stunted growth, soft bones, malformed teeth which decay easily, fragile bones in old people, senility, premature aging, neuritis, senile dementia, rheumy, inflamed eyes, chronic sickness, digestive, nervous and mental ailments, damage to the liver, coronary heart attacks, strokes, diseases of the kindneys, cirrhosis of the liver, high blood pressure, normal heart action, premature wrinkles, intelligence loss, migraine headaches, digestive disorders, obesity, diabetes, cancer, leukemia, nervous disorders, memory defects, severe agitation, infection, pernicious anemia, bleeding; and that the article would keep the blood neutral, assist in blood coagulation, develop and maintain health, happiness, and vigor, assure sufficient energy, prolong the prime of life, boost growth and productive vitality, help one live longer, increase the intelligence quotient, prolong female fertility, aid vision, help teeth form, delay senility, fight disease, aid in healing wounds, keep teeth healthy, and produce healthy blood; and that vitamin E was indisputably important to the heart, nerves, and fertility.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 5–20–60. Consent—claimed by Oro-Vita Corp., Salt Lake City, Utah, and Neoco Corp., Los Angeles, Calif., and released under bond for relabeling and salvaging in compliance with the law. The mineral tablets were subsequently destroyed; the vitamin tablets were reground; and the ground material was packed into drums and labeled.

6500. Vibra Slim device. (F.D.C. No. 41798. S. No. 26–553 P.)

QUANTITY: 56 devices at Minneapolis, Minn.

SHIPPED: 5–13–58, from New York, N.Y., by Modern Aids, Inc.

LABEL IN PART: "Vibra Slim Modern Aids Inc., N.Y."

ACCOMPANYING LABELING: Leaflet entitled "VIBRA SLIM APPETITE SATIENTS FOR CALORIE CONTROL," and newspaper tear sheets entitled "DONALDSON'S SHOWS YOU HOW TO SPOT REDUCE."

RESULTS OF INVESTIGATION: The device was a vinyl covered, cushioned, contoured box, containing an electric motor providing vibration. The newspaper tear sheets were used by the dealer as display placards in the immediate area of the display stock of the device. The shipper of the device had furnished the mat from which the newspaper tear sheets had been prepared.

LIBELED: 6–9–58, Dist. Minn.; removed to Dist. N.J., 9–8–58.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was adequate and effective for trimming and firming bulges; removing excess flabbiness on thighs,

hips, waist, calves, and other parts of the body; stimulating blood circulation; promoting good body condition; removing worry tension; promoting pep, vigor, and energy; melting away nervous tensions and fatigue symptoms by its drugless "tranquilizer" action; spot reducing fatty deposits without starvation diets; relieving rheumatic-like symptoms; and correcting the cause of "fatty problem spots."

DISPOSITION: 11–30–60. Consent—destruction.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 6481 TO 6500

PRODUCTS

[1] (6484) Contains opinion of the court.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

ERRATUM

Change heading of first listing of Drugs and Devices Notice of Judgment No. 6434 to:

6433. Lecithin granules. (F.D.C. No. 44731. S. No. 49–967 R.)

[1] (6484) Contains opinion of the court.
[2] (6487) Injunction issued.

U.S. GOVERNMENT PRINTING OFFICE: 1962

Missing: 6501-6540

D.D.N.J., F.D.C. 6541–6580 Issued June 1962

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6541–6580

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent, or in one case each, after trial by the court or motion for summary judgment; (2) criminal proceedings which were terminated upon pleas of guilty and upon a judgment of guilty after trial; (3) a contempt proceeding for violation of an injunction which was terminated upon a plea of guilty; and (4) injunction proceedings terminated upon the entry of a permanent injunction by consent, and upon the entry of a permanent injunction following the reversal by the appellate court of the judgment of the trial court. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *June 4, 1962.*

CONTENTS*

*For presence of a habit-forming substance without warning statements, see Nos. 6546, 6548; omission of, or unsatisfactory, ingredients statements, Nos. 6546, 6548; an imitation of another drug, No. 6574; failure to bear a label containing an accurate statement of the quantity of the contents, No. 6548; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 6548; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 6558.

637675—62——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6541–6580

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from or its purity or quality fell below that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(c), a word, statement, or other information required by, or under authority of, the Act to appear on the label or labeling of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(d), the article was for use by man and contained a quantity of peyote or other named narcotic or hypnotic substance, or a chemical derivative of such substance, which derivative had been by regulations designated as habit forming, and its label failed to bear the name, and quantity or proportion of such substance or derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(l), the article was composed wholly or in part of a kind of penicillin, or streptomycin, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6541. Dexules timed disintegration capsules. (F.D.C. No. 44602. S. No. 8–880 R.)

QUANTITY: 6 display ctns., containing 12 btls. each, at Buffalo, N.Y.

SHIPPED: 4–15–60, from Hoboken, N.J.

LABEL IN PART: (Btl.) "30 Timed Disintegration Dexules All Day Appetite Suppressant * * * Approved Pharmaceutical Corp. Syracuse * * * New York

Each Capsule Contains: Phenylpropanolamine Hydrochloride 75 mg. Protein Hydrolysate 15 mg. specially prepared to disintegrate over an 8 to 10 hour period for continuous appetite suppression."

ACCOMPANYING LABELING: Display carton, reading in part, "Now! Just One-A-Day Reduce . . . 5–10–20 Pounds Eat All You Want With Dexules * * * Suppresses Appetite All–Day Long"; leaflet entitled "One Week Sample Diets * * * Safe and Sane Reducing Plan."

RESULTS OF INVESTIGATION: Analysis showed that the article contained the labeled amount of phenylpropanolamine hydrochloride. The article had been shipped from Hoboken, N.J., to Syracuse, N.Y., as bulk stock. In Syracuse, N.Y., the article was repacked and then shipped to Buffalo, N.Y.

LIBELED: 6–1–60, W. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was effective as an appetite suppressant, that it would suppress appetite all day long, and that it was a scientific modern method for losing weight through control of appetite; and 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce since an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 3–23–61. Default—destruction.

6542. Barthro injection. (F.D.C. No. 45406. S. No. 46–533 R.)

QUANTITY: 17 boxes, 7 ampules each, at Cleveland, Ohio.

SHIPPED: 11–22–60 and 11–29–60, from Detroit, Mich., by Barry Laboratories, Inc.

LABEL IN PART: (Box) "Barthro (Guanido-Amino-Peptidase) Product No. 2294–5 7 ampules 5 ML. size 2 Q units per 5 ML. each 5 ML. contains enzyme activity not less than 2 "Q" units (Benzyl Alcohol 1.5% as preservative) in water for injection * * * Barry Laboratories, Inc., Detroit 14, Michigan * * * Composition: Barthro is a biocatalyst derived from natural animal material having a direct enzymatic relationship to the substrate of guanine, a purine found in nucleic acid * * * indications: rheumatoid arthritis, osteoarthritis, acute gouty arthritis."

ACCOMPANYING LABELING: Booklet entitled "Barthro Report of Dr. Joseph Fisher, Chelsea, Michigan" and leaflet entitled "Barthro."

LIBELED: 2–1–61, N. Dist. Ohio.

CHARGE: 505(a)—the article was a new drug within the meaning of the law and an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 3–3–61. Default—destruction.

6543. Laetrile (Formula L). (F.D.C. No. 45170. S. Nos. 31–106/7 R.)

QUANITITY: 50 vials of *Laetrile* and 14 vials of *Formula L* at Dallas, Tex., in possession of Taylor Clinic.

SHIPPED: Between 9–30–60 and 10–21–60, from Los Angeles, Calif., by Hale Laboratories, Inc.

LABEL IN PART: (Vial) "Laetrile 500 mg. Sodium 1-mandelonitrile-beta-glucuronoside. Caution: * * * New Drug * * * Hale Laboratories, Inc. * * * Los Angeles 64, California 1423" and "Formula L: Mix with 10 cc sterile water. Give 5 cc each injection. Note: Injections 3 times weekly."

RESULTS OF INVESTIGATION: The 14-vial lot was the "*Laetrile*" product which had been relabeled by the dealer as "*Formula L.*"

LIBELED: 12–28–60, N. Dist. Tex.

CHARGE: 505(a)—the article was a new drug which may not be introduced into or delivered for introduction into interstate commerce since it was sold for investigational purposes and was not being so used, and an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 2–7–61. Default—delivered to the Food and Drug Administration.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR HUMAN USE

6544. Penicillin G tablets. (F.D.C. No. 45448. S. No. 26–857 R.)

QUANTITY: 43 100-tablet btls. at Los Angeles, Calif.

SHIPPED: 8–16–60, from Philadelphia, Pa., by Philadelphia Ampoule Laboratories.

LIBELED: 3–8–61, S. Dist. Calif.

CHARGE: 502(l)—when shipped, the article was composed in whole or in part of penicillin and was from a batch with respect to which a certificate or release had not been issued pursuant to 507 in that effective exemption or supplemental certification of the batch had not been obtained.

DISPOSITION: 3–30–61. Default—destruction.

DRUG FOR VETERINARY USE

6545. Dihydrostreptomycin tablets. (F.D.C. No. 45511. S. No. 61–028 R.)

QUANTITY: 3 drums, each containing 11,500 tablets, 1 drum containing 600 tablets, and 125 100-tablet btls., at St. Joseph, Mo., in possession of United Pharmacal Co., Inc.

SHIPPED: 7–30–58, from Buffalo, N.Y.

LABEL IN PART: (Drum) "Special Formula S/F Tablets—Uncoated Expiration Date July 1960 7–30–58 Manufactured for United Pharmacal Co. * * * St. Joseph, Missouri * * * Formula No. 159,700 Lot 1 UPC–1 * * * Each tablet contains: Dihydrostreptomycin Base (as Sulfate) 50 mg. Pectin 37 mg. Kaolin 417 mg. Hydrated Alumina Powder 126 mg. For treatment of gastroenteritis, enteritis and diarrhea (due to dihydrostreptomycin sensitive organisms) in cats and dogs" and (btl.) "UPCO * * * 'K.P.S.–630' Dihydrostreptomycin Sulfate with Kaolin, Alumina, and Pectin. Each tablet contains * * * Distributed by United Pharmacal Company, St. Joseph, Mo."

RESULTS OF INVESTIGATION: The article in the bottles was repacked and labeled by the dealer after shipment as described above.

LIBELED: On or about 3–16–61, W. Dist. Mo.

CHARGE: 502(l)—while held for sale, the article purported to be and was represented as a drug composed in part of dihydrostreptomycin and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507.

DISPOSITION: 5–5–61. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6546. Various drugs. (Inj. No. 335.)

COMPLAINT FOR INJUNCTION FILED: 6–24–58, N. Dist. N.Y., against Delmar Pharmacal Corp., Rensselaer, N.Y.

NATURE OF BUSINESS: The defendant was engaged in manufacturing, preparing, packing, selling, and distributing directly in interstate commerce, and delivering to the Rand Pharmaceutical Co., Inc., and Previcol, Inc., Rensselaer, N.Y., for sale and distribution in interstate commerce, various articles of drug.

CHARGE: The complaint alleged that the defendant was introducing and causing to be introduced, and delivering and causing to be delivered for introduction into interstate commerce, various articles of drug which were adulterated and misbranded in the following respects:

(a) A number of articles of drug were adulterated within the meaning of 501(b), in that said articles purported to be drugs, the names of which were recognized in an official compendium, the U.S. Pharmacopoeia, and their strength differed from the standards set forth in such compendium;

(b) A number of articles of drug were adulterated within the meaning of 501(c), in that they were not subject to the provisions of 501(b) and their strength differed from, and their quality fell below, that which they purported and were represented to possess;

(c) A number of articles of drug were misbranded within the meaning of 502(a), because of false and misleading statements in the labeling of said articles with respect to the nature and quantity of the ingredients;

(d) A number of articles of drug were misbranded within the meaning of 502(d), in that they were drugs for use by man and they contained a quantity of narcotic or hypnotic substance, or a chemical derivative of such substance, which derivative had been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming, and their labels failed to bear the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming";

(e) A number of articles of drug were misbranded within the meaning of 502(e)(2), in that they were drugs not designated solely by a name recognized in an official compendium and they were fabricated from two or more ingredients, and their labels failed to bear the common or usual name of each active ingredient;

(f) A number of articles of drug were misbranded within the meaning of 502(f)(1), because their labeling failed to bear adequate directions for use in that the recommended or usual dose was omitted; and

(g) A number of articles of drug were misbranded within the meaning of 503(b)(4), in that they were drugs within the meaning of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The complaint alleged further that the adulterated and misbranded condition of said articles of drug resulted from deficiencies in the ingredients of said articles, or the presence in said articles of drug of ingredients in amounts in excess of those declared on the labels, which were due to inadequate manufacturing facilities, lack of identification control, lack of adequate analysis and formulas, or lack of other precautions essential to the compounding of potent

drugs, for example, the *digitalis tablets* contained 74.7 percent of the declared amount of digitalis; the *digitoxin tablets 0.1 mg.* contained 82.9 percent of the declared amount of digitoxin; the *Diphylets tablets, TDC,* contained 90.5 percent of the declared amount of dextro-amphetamine sulfate, were shipped in bulk without the statement "Caution: Federal law prohibits dispensing without prescription" on the label and the label further failed to list the ingredients contained in said article of drug; the labels of the *Reducing tablets—green* and *Reducing tablets—pink* failed to contain the statements "Caution: Federal law prohibits dispensing without prescription," and "Warning—May be habit forming," and the recommended or usual dosage; the *#0 Pink Reducing capsules* were 15.7 percent deficient in dextro-amphetamine sulfate, the two lots of *Del-Bardex #1 Timed Disintegration capsules* were from 23.3 percent to 29 percent deficient in dextro-amphetamine sulfate and were from 20.9 percent to 36 percent deficient in amobarbital; the *Del-Bardex #2 Timed Disintegration capsules* released 80 percent of the active ingredients therein within 2 hours rather than the period of 6–10 hours alleged on the label; the *Special Formula tablets, Cocoa Brown,* were 30 percent deficient in desoxyephedrine hydrochloride; the bulk shipment of *Span RD capsules #1* failed to bear a label containing the statements "Caution: Federal law prohibits dispensing without prescription" and "Warning—May be habit forming" and the recommended or usual dosage; the *Del-O-Bex 30 Timed Disintegration capsules* were 10.4 percent deficient in dextro-amphetamine sulfate and 8.8 percent deficient in phenobarbital; the *Del-O-Bex 15 TDC capsules* were 15 percent deficient in dextro-amphetamine sulfate; the statement, to wit, "Warning—May be habit forming" on the label of the *pentobarbital sodium capsules 1½ gr.* was not in juxtaposition with the name of the drug contained therein; the bulk shipment of *Del Caps 10 mg. TDC capsules* was labeled as containing both 10 mg. and 15 mg. capsules and the major portion of the drug within said capsules was released very rapidly rather than over a 6–10 hour period as alleged on the label; of the six lots of *Del Caps 15 TDC capsules,* four released from 80–94 percent of the dextro-amphetamine sulfate within 2 hours rather than over a period of 6–10 hours as alleged on the label, one lot was 23 percent deficient in dextro-amphetamine sulfate, one lot, a bulk shipment of said drug, failed to bear a label with the statement "Caution: Federal law prohibits dispensing without prescription" and the recommended or usual dosage, and one lot bore a statement on the label, to wit "Each capsule is equivalent to one tablet of 5 mg. Dextro-Amphetamine Sulfate taken two times a day" whereas each capsule contained 15 mg. dextro-amphetamine sulfate and released 10 mg. of the 15 mg. contained therein within two hours; the *Amphetidisin—10 TDC capsules* released 88 percent of the dextro-amphetamine sulfate contained therein within 2 hours rather than over a period of 6–10 hours as alleged on the label; the *Trim-All Caps TDC capsules* were from 23–29 percent deficient in phenylpropanolamine hydrochloride, from 36–38 percent deficient in ascorbic acid and released 90 percent of the active ingredients within two hours; the *dextro-amphetamine sulfate tablets, 5 mg.* contained 25 percent excess dextro-amphetamine sulfate; the *dextro-amphetamine sulfate tablets, 10 mg.* contained 113 percent of the declared amount of dextro-amphetamine sulfate, failed to bear the statements on the label "Caution: Federal law prohibits dispensing without prescription," and failed to state the recommended or usual dosage; the bulk shipment of *Special Formula capsules* failed to bear a label containing the statements "Caution: Federal law prohibits dispensing without prescription," "Warning—May be habit forming" after

the barbiturate declaration, and the recommended or usual dosage; and the *Del Hist 75 mg. capsules* were 11.1 percent deficient in pyrilamine maleate.

The complaint alleged further that the defendant was well aware that its activities were violative of the Act. Thirteen inspections were made of the defendant's plant at Rensselaer, N.Y., by inspectors of the Food and Drug Administration between 10–4–54 and 12–20–57, at which inspections the defendant was informed of certain inadequacies in its control system for the manufacture of articles of drug, namely, the failure to assay raw materials used, failure to retain reserve samples, failure to clearly identify containers, re-use of bulk containers with old labeling, the lack of an adequate checking system to insure that the proper amounts of various chemicals were used in the batches being processed, and the practice of making very few assays of the finished articles. The defendant was warned of the inadequacies encountered. The defendant had been warned further by eleven seizures of articles of drug which were adulterated and misbranded; by hearings pursuant to 305 of the Act; and by a criminal prosecution against the defendant and its former general manager for violation of the Act, which action was terminated upon a plea of guilty by the defendant and its former general manager, resulting in a fine of $750 against the defendant corporation.

DISPOSITION: On 7–22–58, a consent decree of permanent injunction was filed. The consent decree enjoined the defendant from directly or indirectly introducing or causing to be introduced, or delivering or causing to be delivered for introduction into interstate commerce, any article of drug that was adulterated or misbranded under the Act unless and until:

(a) Sufficient qualified and experienced personnel, including supervisory personnel, is employed in the plant to properly operate it.

(b) A properly qualified pharmaceutical chemist is employed to make sufficient analyses of each batch of finished drug to insure that it conforms to the labeling under which it is to be shipped and to the requirements of the National Formulary or U.S. Pharmacopeia or other standard which may be applicable. Lacking this, a representative sample of each finished batch of drugs is submitted to a reliable established outside laboratory for examination prior to shipment.

(c) A system of properly identifying and storing raw materials as they are received at the plant.

(d) Batches of drugs in preparation are not manipulated in an improper manner resulting in unwarranted shortages or overages in the final yield.

(e) Sampling of finished tablets and all other finished products is done in a representative manner to insure the taking of a representative, adequate sample.

(f) Capsules are assayed in finished form rather than in earlier stages of manufacture.

(g) The practice of shipping finished batches of drugs prior to analysis or without analysis is discontinued.

(h) The distribution of new drugs without effective new drug applications is discontinued.

(i) At least one qualified person in the plant has sufficient information concerning the new drug shipped from this plant to eliminate confusions and violations.

(j) Adequate samples of incoming raw materials are taken and appropriate analysis of these samples made.

(k) Preparation of manufacturing records and forms is done with such clarity, care and completeness as to eliminate mistakes and confusion.

(l) Operations involving the weighing out of raw materials and the preparation of formulae and application of labeling are checked by another qualified party in addition to the employee originally performing such duties.

(m) Returned goods are recorded, handled, stored, and again disposed of in a manner which will eliminate uncertainty, confusion, and the possibility of mistakes.

(n) A representative of the U.S. Food and Drug Administration inspects the plant and determines that an adequate control system has been installed embodying all of the herein listed safeguards considered necessary to good pharmaceutical manufacturing practice.

6547. Menestrex capsules. (F.D.C. No. 43564. S. No. 56–778 P.)

QUANTITY: 660 12-capsule btls. and 108 25-capsule btls. at Atlanta, Ga.

SHIPPED: 6–8–59 and 7–13–59, from Nashville, Tenn., by Rex Laboratory.

LABEL IN PART: "Menestrex * * * Contains: Potassium Permanganate Quinine Sulphate."

LIBELED: 9–25–59, N. Dist. Ga.; amended libel filed 2–2–61.

CHARGE: 502(a)—when shipped, the bottle label bore false and misleading representations that the article was an adequate and effective treatment for easing distress in scanty or functionally difficult menstruation; 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use and the article was not exempt from that requirement; 503(b)(4)—while held for sale, the article was subject to 503(b)(1)(B) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: Rex Laboratory, claimant, filed an answer denying that the article was misbranded as alleged and moved for a transfer of the case to another district. On 12–16–59, the court issued the following order:

HOOPER, *District Judge:* "Claimant has moved to transfer the trial of this action to 'a proper district of reasonable proximity to his principal place of business,' his business being located in Nashville, Tennessee, in the Middle District of Tennessee.

"He suggests removal to the Winchester Division of the Eastern District of Tennessee.

"His motion is based upon provisions of *21 U.S.C.A.* § *334(a)*, which makes it mandatory upon the Court in a case of this nature to transfer the case, but there is an exception made in cases 'when such misbranding has been the basis of a prior judgment in favor of the United States in a . . . libel for condemnation proceedings under this chapter.'

"The Government resists the removal upon the sole ground that allegedly there have been 'prior judgments in this district condemning the exact same product.' Attached to the Government response are copies of three libels filed in this district concerning the same shipper and the same product and in two of the libels there is involved the same alleged misbranding, to-wit, that the libels 'are false and misleading since the article is not effective' in the treatment of the ailments involved.

"However, one of these libels was filed October 20, 1948, and it does not appear whether a judgment was taken or whether the proceeding was even opposed. The other libel was filed October 28, 1948, nothing appearing but copy of the libel petition.

"No cases are cited to this Court containing the language in *21 U.S.C.A. § 334(a)* as to 'such misbranding.' However, this Court does not believe that a misbranding made the subject matter of libel proceedings in 1948 can be considered as the same misbranding involved in a libel filed September 25, 1959. As the record now stands the case would have to be removed.

"Removal of the case will be delayed, however, for a period of twenty days, during which the Government may make known to this Court whether or not there is any ground for retaining the case in this Court and constituting 'just cause' under the aforesaid statute.

"If the case is removed it is not the intent of the law that the defendant should be able to select the particular court to which it should be removed, that being left to the discretion of this Court. It would be the purpose of this Court to remove the case to the United States District Court adjoining the one in which defendant's place of business is located which has at the present time the smallest number of cases pending, and therefore defense counsel is directed to ascertain (from official reports of the Administrative Office, or otherwise) which district that would be."

The above order was vacated on 1–22–60, by the following order:

HOOPER, *District Judge:* "Order of Court of December 16, 1959 is hereby vacated and set aside after further study of this question and briefs submitted by all parties.

"The single question confronting the Court is whether or not claimant of the allegedly adulterated goods has a right under 21 U.S.C.A., § 334(a) to transfer this action from the Northern District of Georgia (the only District in which the goods in question were seized) to 'a district of reasonable proximity to the claimant's principal place of business' as provided in said statute.

"The Government, contesting the motion to transfer, has now cited for the first time the case of *Fettig Canning Company* vs. *Steckler*, 188 F. 2d, 715 in which this matter is thoroughly discussed. While the case just cited was a motion to transfer trial of a case such as this pursuant to 28 U.S.C.A., § 1404 (a), a full and complete discussion was also had concerning 21 U.S.C.A., § 334(a) herein involved.

"The point which was made clear, however, in the *Fettig* case, supra, is this:

"The Condemnation proceedings in question constitute an action in rem and the jurisdiction of the Court is limited to the district in which the goods were actually seized. As the goods in the cited case had moved from Indiana to Missouri and were seized in the latter state, the Court held that proceedings could not be transferred from Missouri to Indiana as attempted, for the reason that Indiana was not the jurisdiction where 'the action might have been brought' originally (see p. 717). The Court said that were it assured that the goods were subject to seizure in the Southern District of Indiana it would make no difference.

"While the foregoing applies to the general statute as to transfers, the Court further stated:

> But when we come to § 334, the one here involved, the proceeding is directed at an article and not a person, and while the person who claims to be the owner or interested in the libeled goods is permitted to come in as a claimant, it is not necessary that such person be a party to the proceeding. All that is required is that the libeled articles be found in the District, and this limitation upon jurisdiction appears to have been imposed deliberately and not as a result of any inadvertence.

"In the cited case it is also pointed out that 'Congress has made no provisions by which such a decree could be made effective beyond the territory of the district wherein the case was tried.'

"While § 334(a) does contain a proviso that no libel for condemnation shall be instituted for misbranding 'if there is pending in any court a libel for condemnation proceedings . . . based upon the same misbranding,' and also provides that 'not more than one such proceeding shall be instituted if no such proceeding is pending,' there is an exception to the effect that such limitations shall not apply 'when such misbranding has been the basis of a prior judgment in favor of the United States in a libel for condemnation proceedings

under this chapter.' While a great deal of discussion has been had by counsel for both sides on the question of venue, it seems to this Court that it pertains not to venue so much as to multiplicity. It makes it clear, however, that the fact, as shown by this record, that there have been several prior judgments against the same claimant growing out of the same misbranding of the same articles, that is no obstacle to the present proceedings. The language relied upon by defendant commanding a transfer of the case, must be taken however in the light of the limitation that it applies 'in any case where the number of libels for condemnation proceedings is limited as above provided.' The language would seem to indicate that if there were more than one seizure it would be the duty of the trial judge to transfer the action from a jurisdiction remote from the claimant's residence to one in reasonable proximity to the same. However, no ruling to this effect is made as the Court could be in error as to the meaning of the language.

"The Court's refusal to granting the change of venue is therefore placed upon the ground that this is an action in rem and the jurisdiction of this Court is based upon the fact that the seizure was had in this district and this Court cannot transfer the case to another district where no seizure was had, even though a seizure in such other district could have been had.

"Motion for change of venue is denied."

The Government subsequently filed written interrogatories which were answered by the claimant on 6–6–60. Thereafter, the libel was amended to include the charges of misbranding under 502(f)(1) and 503(b)(4) as set forth above, and, on 3–7–61, a motion for summary judgment was filed by the Government on the basis that there were no genuine issues of material fact precluding judgment for the Government. On 3–22–61, the court granted the Government's motion for summary judgment and ordered the article condemned and destroyed.

6548. Peyote and peyote extract capsules. (F.D.C. No. 44571. S. Nos. 33–880 R, 34–806/7 R.)

QUANTITY: 6 ctns. containing a total of 294 lbs. and reused paper bags containing a total of 20 lbs. of *peyote;* and 29 unmarked envelopes containing 5 capsules each of peyote extract, at New York, N.Y.

SHIPPED: On 4–22–60, the 294-lb. lot and on 12–17–59, the 20-lb. lot, from Laredo, Tex., by Smith's Cacti Ranch.

LABEL IN PART: (Ctn.) "From: Smith's Cacti Ranch, P.O. 736, Laredo, Texas To: Barron Bruchlos, 234 Mulberry Street, New York, New York * * *"; (bag) "French Roast Flavor Cup Coffee * * * 1 Lb. Net."

RESULTS OF INVESTIGATION: Examination of the article in the 294-lb. and 20-lb. lots showed it to be *peyote.* The article in the capsules contained alkaloids of peyote and had been prepared from some of the *peyote* in the 20-lb. lot under the direction of the consignee of the articles, Barron Bruchlos, t/a Cart Wheel Coffee Shop.

LIBELED: 5–17–60, S. Dist. N.Y.

CHARGE: 502(b)—when shipped and while held for sale, the articles failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of the contents; 502(d)—the articles were a hypnotic substance, namely, *peyote,* and their labels failed to bear the name, quantity, or proportion of such substance and, in juxtaposition therewith, the statement "Warning—May be habit forming"; 502(e)(1)—the labels of the articles failed to bear the common or usual name of the articles; 502(f)(1)—the labeling of the articles failed to bear adequate directions for use; 503(b)(4)—the articles were drugs

subject to 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: The consignee of the articles appeared as claimant and filed an answer denying that the articles were subject to seizure. Subsequently, the Government filed interrogatories. On 12–6–60, the claimant died, and, on 1–18–61, the proctor for the claimant having consented, the court entered a decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6549. Lecithin capsules, strawberry oil, Minovals capsules, and Alma-Cado Oil. (F.D.C. No. 44654. S. Nos. 50–255 P, 50–257 P, 50–259 P, 50–262 P.)

INFORMATION FILED: 11–23–60, S. Dist. Ohio, against Roy C. Elkins, Miami, Fla.

ALLEGED VIOLATIONS: Between 10–7–59 and 10–9–59, while the articles were being held for sale at a health food store in Cincinnati, Ohio, after shipment in interstate commerce, the defendant, in the course of sales talks given by him at a Cincinnati hotel, caused oral representations to be made holding the articles out as a treatment for various diseases, symptoms, and conditions as hereinafter described, which acts resulted in the articles being misbranded.

LABEL IN PART: (Jar) "RoyelkinS 100 CAPSULES LECITHIN Suspended in Soybean Oil Distributed by ROY ELKINS HEALTH FOODS P.O. Box 782 Miami, Fla."; (btls.) "Roy Elkins Strawberry Oil Distributed by ROY ELKINS—BEVERLY HILLS, CALIF. NET CONTENTS 4 FL. OZ."; "RoyelkinS 100 CAPSULES MINOVALS WITH WHEAT GERM OIL Distributed by ROY ELKINS HEALTH FOODS P.O. Box 782 Miami, Fla."; and "Roy Elkins Famous ALMA-CADO OIL CONTAINS NO CHOLESTEROL NET CONTENTS 8 FL. OZS. PRICE $2.50 Distributed by ROY ELKINS P.O. Box 782, Miami 1, Florida."

CHARGE: 502(f)(1)—the labeling of the articles failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the articles were intended, namely, (*lecithin capsules*) disorders of the eyes, ears, circulatory system and cramps; (*strawberry oil*) rheumatoid conditions and neoplasms; (*Minovals capsules*) ulcers; and (*Alma-Cado Oil*) arthritis, disorders of the veins, and warts, which were the diseases, symptoms, and conditions for which the articles were held out by the defendant in the course of the above-mentioned sales talks.

PLEA: Guilty.

DISPOSITION: 4–7–61. Fine of $250 on each of the 4 counts of the information, with the fine on 3 of the counts being suspended on condition that the defendant not re-enter the health food lecturing business.

6550. Visan Assurance Food Supplement. (F.D.C. No. 44321. S. No. 61–265 P.)

INFORMATION FILED: 9–27–60, E. Dist. Mich., against Jean Kalin, Detroit, Mich.

ALLEGED VIOLATION: On 8–11–59, the defendant, in the course of a sales talk to persons present, made oral representations holding out *Visan Assurance Food Supplement* capsules and tablets as a treatment for the diseases, symptoms, and conditions set forth below, which acts resulted in the articles being misbranded while held for sale.

*See also Nos. 6546–6548.

LABEL IN PART: (Ctn.) "Visan Assurance Food Supplement Contents 60 Red Vitamin Capsules 180 Green Mineral Tablets 1 month supply for 1-adult or teenager."

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which they were intended, namely, arthritis, eczema, hardening of the arteries, hay fever, nervous stomach, high blood pressure, sinus diseases, migraine headache, heart disease, run-down condition, constipation, stiff neck, swollen knees and fingers, asthma, coughs, nervous conditions, goiter, colitis, sugar diabetes, and sore and bleeding hands, which were the diseases, symptoms, and conditions for which said article was held out to the persons present at the aforesaid sales talk.

PLEA: Not guilty.

DISPOSITION: On 1–11–61, the defendant was found guilty after a trial by the court without a jury, and, on 3–7–61, was fined $250 and placed on probation for 2 years.

6551. Tri-Wonda Treatment (Tri-Wonda Nos. 1, 2, and 3). (Inj. No. 270.)

COMPLAINT FOR INJUNCTION FILED: 3–3–54, S. Dist. Miss., against Lela S. Wier, t/a Wonda Products Co., Jackson, Miss.

NATURE OF BUSINESS: The defendant was engaged in distributing and selling the drug "Tri-Wonda." This drug consisted of three component parts which were packed in separate containers. One bottle of "Tri-Wonda No. 1," two cans of "Tri-Wonda No. 2," and three bottles of "Tri-Wonda No. 3" constituted a "*Tri-Wonda Treatment*." "Tri-Wonda No. 1" was a combination of dilute hydrochloric and dilute nitric acid with traces of tartaric and acetic acids; "Tri-Wonda No. 2" was a mild laxative containing cream of tartar, senna, sulfur and phenolphthalein; and "Tri-Wonda No. 3" consisted of a 44 percent alcohol solution of fluid extract of Jamaica dogwood, thiamine hydrochloride, and wild cherry flavoring. The drug was sold by the defendant for use by sufferers of arthritis, rheumatism, and bursitis.

CHARGE: The complaint alleged that the drug "Tri-Wonda" was introduced into interstate commerce, and held for sale after shipment in interstate commerce, by the defendant, with labeling containing false and misleading representations that the drug was effective in the treatment of muscular aches, pains, soreness, stiffness, swellings, bursitis, rheumatism, and arthritis.

The complaint alleged further that the defendant was engaged in distributing, selling, and introducing and delivering for introduction into interstate commerce, the drug "Tri-Wonda" which was misbranded within the meaning of 502(a) of the Act in that its labeling contained false and misleading statements.

The complaint alleged further that the defendant was associating and causing to be associated with the drug "Tri-Wonda," after the drug had been shipped in interstate commerce and while it was held for sale, labeling containing false and misleading statements concerning the drug's therapeutic efficacy; which acts of the defendant resulted in "Tri-Wonda" being misbranded within the meaning of 502(a) of the Act.

It was alleged further that, if the defendant were restrained from using the labeling complained of, she would, unless enjoined, continue to merchandise the "*Tri-Wonda Treatment*" without the use of such labeling. In that case, the "*Tri-Wonda Treatment*" would be misbranded within the meaning of 502(f)(1) of the Act, if it were intended for use in the treatment of muscular

aches, pains, soreness, stiffness, swellings, bursitis, rheumatism, and arthritis since its labeling would not bear adequate directions for use in the treatment of all of the diseases and conditions for which the article was intended.

DISPOSITION: On 3–15–54, the defendant filed an answer to the complaint, denying that "Tri-Wonda" was misbranded and denying that she had represented to prospective purchasers in the labeling of the drugs that "Tri-Wonda" had any effectiveness beyond the capacity to give relief from certain symptoms and distress accompanying arthritis and rheumatism. The defendant's answer further stated that the drug would provide some or all such relief in a substantial proportion of cases.

On 8–5–54, upon agreement of counsel in open court, the court ordered the consolidation for trial of this injunction action with a seizure action in which 11 100-lb. drums and 1,526 4-oz. cans of "Tri-Wonda No. 2," and 7,306 2-oz. bottles of "Tri-Wonda Nos. 1 and 3" had been seized (see D.D.N.J. No. 6568). Thereafter, both sides filed written interrogatories and the Government filed two series of requests for admissions. Trial on the issues of both the libel and the injunction began on 9–26–55. There were recesses, and the testimony was completed on 6–21–56, after nearly 7 weeks of actual trial. The case was taken under advisement by the court.

On 10–22–58, the court confirmed the condemnation of the articles seized in the libel action, but found that the Government was entitled to only partial relief in the injunction action. The court made the following findings of fact and conclusions of law:

MIZE, *District Judge:*

FINDINGS OF FACT

"1. The defendant, Lela S. Wier, trading as the Wonda Products Co., Jackson, Mississippi, at the time of filing of this suit and for sometime past, has been introducing and causing to be introduced into interstate commerce at Jackson, Mississippi, a combination of three drug products called the 'Tri-Wonda Treatment,' intended for use in the treatment of arthritis, rheumatism and bursitis.

"2. The 'Tri-Wonda Treatment' is recommended in its labeling for the treatment of arthritis, rheumatism, bursitis, neuritis, neuralgia, sciatica, and for muscular aches, pains, soreness, stiffness, swelling and limitation of motion which accompany these diseases (Gov. Exs. 4, 15, 26, 27); spurs in the heel, and sciatic cramps and pains (Gov. Ex. 26).

"3. The 'Tri-Wonda Treatment' is composed of Tri-Wonda No. 1, Tri-Wonda No. 2, and Tri-Wonda No. 3.

"4. Tri-Wonda No. 1 is a combination of dilute hydrochloric and dilute nitric acids with traces of tartaric and acetic acids. Dosage recommendation is six drops in four ounces of water after meals. (Gov. Ex. 4.)

"5. Tri-Wonda No. 2 is a combination of tartar, senna, sulphur and phenolphthalein, a mild laxative to be taken at bed time, one teaspoonful mixed in ½ glass of water. (Gov. Ex. 4.)

"6. Tri-Wonda No. 3 consists of fluid extract of Jamaica dogwood, thiamine hydrochloride, and wild cherry flavoring dissolved in 44% alcohol. Twenty-five drops in two ounces of water are to be taken ½ hour before meals. (Gov. Ex. 4.)

"7. About 1900, Rev. H. A. Hall, a minister of the gospel, had a formula for a medicine which he labeled 'Hall's Muneac,' 'Hall's Laxative Powder,' and 'Hall's Compound.'

"8. 'Hall's Muneac' was recommended for a long list of diseases, including Bright's disease, diabetes, neuralgia, hookworm, high blood pressure, indigestion, gallstones, ulcerated stomach, dengue fever, common cold, influenza, tonsillitis, scarlet fever, as well as arthritis and rheumatism. (Gov. Ex. 88.)

"9. In 1938, Rev. H. A. Hall and his wife, Mrs. Hallie B. Hall, stipulated with the U.S. Post Office Department to discontinue using the mails for

marketing Hall's remedies. (Gov. Ex. 93.) Thereafter, these drugs were compounded and sold only in Tampa, Florida, at the home of the Halls.

"10. In 1950, the defendant, Mrs. Lela S. Wier, who had rheumatoid arthritis, first took the Hall products and she attributed improvement in her condition to the Hall drugs.

"11. Three months thereafter, she obtained the formula for these three Hall products and, after making some changes in it, began marketing them for use in the treatment of arthritis and rheumatism under the name of 'Tri-Wonda.'

"12. The formulas of the Tri-Wonda products are substantially the same as the Hall medications except that the strength of the acids and the dosage of Tri-Wonda No. 1 are reduced, and thiamin hydrochloride has been added to Tri-Wonda No. 3.

"13. In 1951, the defendant was told by physicians of the Food and Drug Administration in Washington, D.C., that Tri-Wonda was worthless in treating arthritis. In 1952, she was advised by officials of the Administration that the labeling of Tri-Wonda which promoted it as an arthritic remedy was false and misleading.

"14. In 1953, in cause No. 1929, the United States seized a large stock of the Tri-Wonda drugs, 'Special Bulletin,' and 'Dear Friend' letters (Gov. Ex. 40), charging that the bulletin and letters were labeling and falsely represented these drugs to be an adequate and effective treatment for arthritis, rheumatism and bursitis.

"15. In 1954, the United States filed its complaint in cause No. 2106, for injunction in this proceeding charging that the labeling of the Tri-Wonda drugs suggested and represented them to be effective in the treatment of muscular aches, pains, soreness, stiffness, swellings, bursitis, rheumatism and arthritis, which labeling was false and misleading since these drugs were not effective in the treatment of these conditions. The injunction proceeding and the seizure were tried concurrently. In March 1954, defendant answered the complaint, in which answer the defendant, Lela S. Wier, specifically denied all of the allegations that the labeling of the Tri-Wonda medicines has been, is now, or will be misbranded in violation of the various statutes cited, and specifically denied that the representations in the labeling of such products are false and misleading. The answer alleges that, in carrying on her business, the defendant has truthfully represented in the labeling and advertising of her drug products to prospective purchasers thereof that the three drug products designated 'Tri-Wonda No. 1,' 'Tri-Wonda No. 2' and 'Tri-Wonda No. 3,' when taken in accordance with the directions, have the capacity to give relief from certain symptoms and distress accompanying bursitis, rheumatism and arthritis, including: pain, soreness, the swelling of tissues around joints; the loss of freedom of motion resulting from pain, soreness and the swelling of tissues around the joints; the loss of general well being; constipation; and the deficiency of vitamin B_1 associated with arthritis and rheumatism; and that said drugs, when used in accordance with the directions by persons so suffering, have provided, do provide, and will provide some or all of the foregoing relief in a substantial proportion of cases.

"16. Defendant has been, and was at the time of filing the complaint herein, introducing the 'Tri-Wonda treatment' into interstate commerce, accompanied by letters, pamphlets, and circulars which suggest and recommend that these drugs are effective in the relief of muscular aches, pains, soreness, swelling, arthritis, rheumatism, bursitis and sciatica.

"17. Defendant has advertised the 'Tri-Wonda treatment' in over 5,000 newspapers under the title 'ARTHRITIS?', stating that she has been restored to active life and received wonderful relief. Readers were invited to write for details. (Gov. Ex. 5.)

"18. In response to inquiries from prospective customers various types of promotional material have been sent out, including 'Special Bulletin' (Gov. Exs. 6, 7, 8, 45), 'Dear Friend' letters (Gov. Exs. 9, 14, 16, 44) prior to March 1953, and since that time other form letters of various types (Gov. Exs. 10, 11, 12, 13), testimonial letters (Gov. Ex. 15), personal letters containing many stock paragraphs used to answer various inquiries (Gov. Exs. 18, 19, 20, 21, 22, 23, 24, 26, 36, 42, 81), leaflets containing customers' pictures and testimonials (Gov. Exs. 26, 27), and leaflets entitled 'Attention Arthritics' (Gov. Ex. 72).

"19. Some of the letters, leaflets and testimonials used in promoting and marketing the 'Tri-Wonda treatment,' suggest and represent the three drugs to be an adequate and effective treatment for muscular aches, pains, soreness, stiffness of the joints, swelling of tissues around the joints, loss of freedom of motion of the joints, and for arthritis, rheumatism and bursitis.

"20. A substantial number of persons who read those letters, testimonials and leaflets receive the impression that the 'Tri-Wonda treatment' is a cure for all forms of arthritis and rheumatism. (Dr. Mosel, Gov. Exs. 66, 67, 68, 69, 70.)

"21. There are many types of rheumatic diseases. The cause of some are known; that of others, unknown. Accepted medical treatment for the various forms of rheumatic diseases varies widely.

"22. It is a characteristic of many rheumatic diseases that they subside spontaneously for periods varying from a few days to several years; some regressions are permanent. On these occasions the patient is free of pain, swelling, soreness, and limitation of motion. Relapses are frequent with the return of the disease and resumption of the symptoms stated. These remissions and relapses are generally recurrent over periods of years.

"23. Specific medications and treatments can cure some types of rheumatic diseases including gouty, tubercular and gonococcic arthritis, and arthritis due to other specific types of infection. Delay in obtaining proper treatment for these types of arthritis may result in destruction of the affected joints and permanent crippling.

"24. At the present time there is no known cure for rheumatoid arthritis and osteoarthritis, although extensive research work is being conducted in many hospitals, clinics and laboratories. Approximately 80% of rheumatic patients suffer from these two types of arthritis.

"25. The medical profession use the salicylates, gold salts, cortisone, hydrocortisone, ACTH, and other steroid type drugs in the treatment of rheumatoid arthritis and osteoarthritis. Physiotherapy and surgery, including immobilization of joints, are sometimes resorted to in severe cases.

"26. The Government contends that the defendant has suggested and represented in the labeling that the Tri-Wonda medicines are effective in the treatment of muscular aches, pains, soreness, stiffness, swellings, bursitis, rheumatism and arthritis, that these statements are false and misleading in that the Tri-Wonda medicines are not effective in the treatment of such conditions and diseases.

"27. The defendant contends that she has truthfully represented, in the labeling of her products to prospective purchasers, that the Tri-Wonda medicines, when taken in accordance with the directions, have the capacity to give relief from certain symptoms and distress accompanying arthritis, rheumatism and bursitis, including: pain, soreness; the swelling of tissues around joints; the loss of freedom of motion resulting from pain, soreness, and the swelling of tissues around joints; the loss of general well being; constipation; and the deficiency of vitamin B_1 associated with arthritis, rheumatism and bursitis; and that said drugs, when used in accordance with the directions by persons so suffering, have provided, do provide, and will provide some or all of the foregoing relief in a substantial proportion of cases, and that she has, in good faith, without intent to defraud, continuously made a sincere, honest effort to avoid any false or misleading representation in the labeling of the Tri-Wonda medicines, directly or by implication; that it has never been and is not now her desire or intention to make any false or misleading representation of these products; that it is her intention at all times to comply with the law, particularly the provisions of the Federal Food, Drug and Cosmetic Act. That in the labeling of her products, the defendant stands ready to correct and offers to correct the labeling by removal of such representations.

"28. The court finds that the 'Special Bulletin' (Gov. Exs. 6, 7, 8) and the 'Dear Friend' letter (Gov. Ex. 9) contain statements representing and suggesting by implication that the Tri-Wonda medicines are a cure or remedy for any and all forms of rheumatism; that the evidence establishes that the Tri-Wonda medicines do not constitute a cure or remedy for any and all forms of rheumatism; and such representation is, therefore, false. However, this representation was made in good faith, without intent to defraud any purchaser or prospective purchaser. I further find that the use and distribution

of the printed leaflet entitled 'Special Bulletin,' and the 'Dear Friend' letter were abandoned and discontinued by the defendant sometime in 1953 and before the complaint for injunction was filed, and have not been used or distributed by the defendant since that date to the present time.

"29. The court finds that the Government has failed to meet the burden of proof and establish that the statements in some of the labeling used and distributed by the defendant, Lela S. Wier, the correspondence and the printed leaflets, are false and misleading, and has failed to prove that the Tri-Wonda medicines, when taken according to directions are not beneficial in a substantial number of cases in the treatment of some of the symptoms of arthritis, rheumatism and bursitis, including: pain, soreness, the swelling of tissues around the joints; the loss of freedom of motion resulting from pain, soreness and the swelling of tissues around the joints; the loss of general well being; constipation; and the deficiency of vitamin B_1 associated with arthritis, rheumatism and bursitis."

CONCLUSIONS OF LAW

"1. The Court has jurisdiction of the parties and the subject matter of this proceeding under the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 332(a).

"2. The circulars, leaflets, testimonials, form letters, and letters consisting of stock paragraphs which have been and are now used in the sale and distribution of the 'Tri-Wonda treatment' constitute 'labeling' within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321(m).

"3. That some of the labeling of the 'Tri-Wonda treatment' represents and suggests that the drugs are effective in the treatment of arthritis, rheumatism, bursitis, sciatica and neuritis, and the muscular aches, pains, soreness, stiffness, swelling and loss of freedom of motion of joints which accompany said diseases, which labeling is false and misleading within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 352(a), in that the 'Tri-Wonda treatment' is not effective in the treatment of all these diseases and conditions.

"4. The 'Special Bulletin' and the 'Dear Friend' letter represent and suggest by implication that the Tri-Wonda medicines are a cure or remedy for any and all forms of rheumatism and such representation in the labeling is false and misleading within the meaning of U.S.C. Title 21, Section 352(a).

"5. The defendant, Lela S. Wier, an individual trading as the Wonda Products Company, may continue to distribute and sell the Tri-Wonda medicines in interstate commerce provided the labeling thereof is not false and misleading and is limited to representations that the Tri-Wonda medicines, when taken according to directions, are beneficial in a substantial number of cases in the treatment of the following symptoms of rheumatoid arthritis, rheumatism and bursitis: pain, soreness, the swelling of tissues around joints; the loss of freedom of motion resulting from pain, soreness, and the swelling of tissues around joints; the loss of general well being; constipation; and the deficiency of vitamin B_1, associated with arthritis, rheumatism and bursitis.

"6. The Government is entitled to a permanent injunction restraining the interstate distribution of Tri-Wonda No. 1, No. 2 and No. 3 labeled in any manner which represents or suggests them as a treatment for any rheumatic disease except as set out and limited in the foregoing opinion and conclusions of law.

"7. The Government is entitled to a permanent injunction restraining the interstate distribution of Tri-Wonda No. 1, No. 2 and No. 3 unless the labeling of each bears adequate directions for use in the treatment of all diseases, symptoms or conditions for which these drugs are intended. 21 U.S.C. 352(f)(1).

"Order will be settled in accord herewith."

A decree of permanent injunction which granted the Government partial relief was filed on 1–16–59. Both Government and the defendant filed notices of appeal to the United States Court of Appeals for the Fifth Circuit, which heard the appeals on 4–26–60.

On 8–8–60, the court of appeals handed down the following opinion reversing the judgment of the district court (281 F. 2d 850):

TUTTLE, *Circuit Judge:* "This is an appeal by the United States from an order granting an injunction against some, but not all, of the claims of the appellee used in the interstate sale of her patent medicines, Tri-Wonda No. 1, Tri-Wonda No. 2, and Tri-Wonda No. 3.[1]

"These medicines were sold by appellee for use by sufferers of arthritis, rheumatism and bursitis. The Government's appeal results from the fact that the decree of the trial court enjoined the defendant from distributing the products in interstate commerce when misbranded by representing that they or any similar drug are 'a cure or adequate treatment for any form of arthritis or rheumatism' but which decree expressly stated that 'she could continue to introduce the drug into interstate commerce provided the labeling thereof was not false and misleading, permitting her to represent that the Tri-Wonda medicines, when taken according to directions, are beneficial in a substantial number of cases in the relief of some symptoms of rheumatoid arthritis, rheumatism and bursitis, such as pain, soreness, the swelling of tissues around the joints; the loss of freedom of motion resulting from pain and soreness accompanying rheumatoid arthritis; the loss of general well being; constipation; and the deficiency of vitamin B–1 associated with arthritis, rheumatism and bursitis . . . .'

"The United States complained of the permissive part of the order and the failure of the court to enjoin the representation that 'the drugs were beneficial in a substantial number of cases in the relief of some symptoms of rheumatoid arthritis, rheumatism and bursitis such as pain, soreness, the swelling of tissues around the joints, and the loss of freedom of motion resulting from pain and soreness accompanying rheumatoid arthritis' on two grounds: (1) the acts enjoined by the court could not be distinguished from the acts permitted and thus 'the decree contains inconsistencies and ambiguities which make it unenforceable,' and (2) such representations as are permitted by the Court are wholly unjustified by the evidence of record.

"The trial court made explicit findings of fact, which included the following:

> . . . that the evidence establishes that the Tri-Wonda medicines do not constitute a cure or remedy for any and all forms of rheumatism; and such representation is, therefore, false. . . .

Finding No. 29, to which the Government directs its attack, is as follows:

> 29. The court finds that the Government has failed to meet the burden of proof and establish that the statements in some of the labeling used and distributed by the defendant, Lela S. Wier, the correspondence and the printed leaflets, are false and misleading, and has failed to prove that the Tri-Wonda medicines, when taken according to directions are not beneficial in a substantial number of cases in the treatment of some of the symptoms of arthritis, rheumatism and bursitis, including: pain, soreness, the swelling of tissues around the joints; the loss of freedom of motion resulting from pain, soreness and the swelling of tissues around the joints; and loss of general well being; constipation; and the deficiency of vitamin B_1 associated with arthritis, rheumatism and bursitis.

"Among the three questions presented by appellee in her brief is the following: 'Is Finding of Fact No. 29 in the decision below contrary to the overwhelming evidence, so that it is completely erroneous?' In our view of the case this question must be answered in the affirmative, thus making unnecessary an answer to the first contention of the Government.

"In approaching the problem as to the duty and power of the appellate court when called upon to review a finding of fact by the trial court, sitting without a jury, we start with the basic rule:

[1] Tri-Wonda No. 1 is a combination of dilute hydrochloric and dilute nitric acids with traces of tartaric and acetic acids. Tri-Wonda No. 2, which is a combination of cream of tartar, senna, sulphur, and phenolphthalein, is a mild laxative. Tri-Wonda No. 3 consists of fluid extract of Jamaica dogwood, thiamin hydrochloride (vitamin B_1) and wild cherry flavoring dissolved in 44% alcohol.

Rule 52. FINDINGS BY THE COURT.

(a) Effect. In all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon and direct the entry of the appropriate judgment; and in granting or refusing interlocutory injunctions the court shall similarly set forth the findings of fact and conclusions of law which constitute the grounds of its action. Requests for findings are not necessary for purposes of review. Findings of fact shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses. . . .

Although the trial court's finding here was stated in terms of a failure of the Government 'to meet the burden of proof and establish that the statements . . . are false and misleading,' we consider this simply as a finding against the Government on the evidence.

"It will at once appear to anyone dealing with an effort to prove that certain chemicals do or do not have a therapeutic effect on the human body, that the investigator, here the trial court, must do more than simply pass upon the credibility of the witnesses in ascertaining whether there is any evidence substantial enough to support the finding pro or con. For instance, we have held in *United States* v. *Hoxsey Cancer Clinic*, 5 Cir., 198 F. 2d 273, that the testimony of a layman, either that he is suffering from cancer or that he has been cured of cancer, however honestly given and however firmly believed, does not rise to the dignity of substantial evidence. It follows that the same is true as to any disease whose presence or cure can be ascertained only by persons trained in medical science and by the use of scientific aids or surgery.

"We think that what has been said as to the diagnosis of disease by a layman, even though he be a sufferer, applies with equal force to an opinion given by a sufferer that his relief from pain or relief from other symptoms of a disease is the result of the taking of specific medicines. Certainly a statement by a patient whose diet is not otherwise controlled or brought into the inquiry, who may be taking other medicines at the same time, and particularly in a disease which has a high rate of remissions, that his pain, swelling or limitation of movement has been helped by Tri-Wonda, cannot amount to substantial evidence, even though it be technically admissible.

"Dealing with just such an appeal by the Government from a finding by the trial court that it 'had failed to carry the burden of establishing the truth of the allegations of its complaint' this Court, in the Hoxsey case clearly established the law which must guide us here.

"There, as here, highly qualified experts in the field of medicine involved (there, cancer, here arthritis) testified uniformly that the disease could not be diagnosed without the use of scientific aids not used by the witnesses for the appellee in either case; that the cause of the disease was unknown and the known treatment of it of very doubtful efficacy at best; that great amounts of research had been carried on to broaden the field of knowledge of the medical profession as to cause and cure. There, as here, there was testimony on behalf of the Government resulting from clinical studies made by those medical men who had specialized in the field, which tests were made with controls and with care to make most likely the possibility of an objective ascertainment of the truth and there was also testimony for the respondent from others not specialists in the field based on clinical tests made in disregard of the major recognized safeguards to an objective test. There, as here, pharmacologists, those skilled in the knowledge of the effect of chemicals on the human organs and functions, testified to the worthlessness of the drug in question when used as directed for the stated purposes. There, as here, there were doctors and patients who nevertheless testified, obviously without the necessary foundation for basing an opinion, that the medicine did offer relief or cure.

"Notwithstanding the testimony which, in another type of case, it might be said would create a conflict, the Court, speaking through Judge Russell, said:

Thus, even if it be assumed, arguendo, that there is some measure of conflict in the evidence relating to the falsity of the specific representa-

> tions referred to above, still, it is clear that a finding that such representations are true is not supported by substantial evidence.

And, further:

> We think this so-denominated conflicting evidence, wholly insufficient to cast such doubt upon the testimony adduced in behalf of the Government as to authorize the trial court to find that the Government had failed to carry the burden of establishing the truth of the allegations of its complaint. 198 F. 2d 273, 280, 281.

"In this case the evidence on behalf of the United States was impressive. Specialists in the field of arthritic diseases, active in arthritic research and members of the learned societies dealing with this medical specialty, one of whom testified that he had treated approximately 40,000 arthritic patients, one orthopedic surgeon and two research specialists, testified without equivocation that the ingredients of these three patent medicines in the quantities recommended for treatment were without therapeutic value either in the treatment of, or alleviation of the symptoms of arthritis.

"In addition to the foregoing evidence three pharmacologists, experts in the field of drugs and their effect on the human system, also testified that the ingredients of Tri-Wonda were not recognized in any of the literature or teachings of the profession for the treatment of, or alleviation of the suffering, from arthritic diseases. They further gave their opinion that they had no value in relation to such disease.

"This evidence was countered, on behalf of the appellee, by five general practitioners, all of whom professed not to be specialists in the field, and all of whom made disparaging remarks concerning their own qualifications either to diagnose or treat the several types of arthritic diseases. Their testimony was almost without exception based upon tests [2] on patients sent to them by the appellee or on patients who had diagnosed their own condition and asked for treatment by obtaining a free course of medicine furnished by appellee.

"Appellant's brief is replete with specific excerpts of testimony relating to cases testified about by these general practitioners and their patients. Strikingly, appellee opens its brief with the following statement:

> Except for conclusions of the pleader as to the effect of evidence adduced, appellee believes the case is fairly stated in a part of the brief for appellant. Only the first page statement is accepted because the remainder of the statement by appellant is argument in advance.

Yet nowhere in the brief is a single statement of fact contained in the brief of the United States refuted or otherwise attacked by the appellee. We have carefully read the record references to the testimony of the 35 to 40 case histories which are carefully analyzed in the Government's brief and have found the conclusions drawn by the Government are completely accurate as to the effect of the testimony.

"In brief, it must be said that the evidence of not one of the five general practitioners rises to the quality necessary to constitute substantial evidence when considered in the light of the other evidence in the record. This is so because either the medical witnesses thoroughly disqualified themselves as having any skill in either diagnosis or treatment of the arthritic diseases or because their evidence as to the effectiveness of Tri-Wonda in alleviating pain, reducing swelling or improving mobility of joints was either merely a repetition of statements made to them by the patients, or because the record clearly discloses that there was no diagnosis of the existence of the disease either before or after the so-called treatment, or for both reasons. For instance one of the doctors testified: 'Everyone of these patients already had their own diagnosis made.' They all completely ignored the important differences in the cause and treatment normally accorded the different types of arthritis. They all testified they knew of no literature in the field that suggested the component parts of these medicines, taken singly or together, as being efficacious in the treatment of the disease.

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[2] The circumstances under which these tests were given so far lacked the normal controls recognized even by these witnesses as proper to an objective ascertainment of the worth of a new drug that they cannot really be called "clinical tests."

"Even though otherwise not objectionable, the testimony of these witnesses amounted to nothing more than testimony from their individual personal experience. As to this kind of medical testimony Wigmore's comment is pertinent:

> To allow any physician to testify who claims to know solely by personal experience is to appropriate the witness stand to impostors. Medical science is a mass of transmitted and collated data from numerous quarters; the generalizations which are the result of one man's personal observation exclusively are the least acceptable of all. The law must recognize the methods of medical science. It cannot stultify itself by establishing, for judicial inquiries, a rule never considered necessary by the medical profession itself. It is enough for a physician, testifying to a medical fact, that he is by training and occupation a physician; whether his source of information for that particular fact is in part or entirely the hearsay of his fellow practitioners and investigators, is immaterial. Wigmore, Evidence, 3d ed., Vol. III, § 687.

"In addition to the testimony of the general practitioners above referred to, appellee introduced as a witness a Dr. Mary Gray, also lacking any special qualifications in the field of arthritic diseases, who merely undertook to interview a number of patients to whom she was sent by Mrs. Wier, the appellee. Her survey was, of course, based solely on the statements made to her by the customers who had already used the medicine before they were interviewed by her. A number of these persons who were reported by Dr. Gray to have stated that their condition had improved, testified as witnesses at the trial in which they repudiated such testimony.

"Finally, a Dr. Nellie Watts testified that she had searched the literature in the arthritic field and, based solely on this search she had made, she concluded that some of the chemicals in these medicines might act as a diuretic and, by lowering the water content of the body generally, reduce swelling of the joints. In view of the fact that two of the writers of the articles on which Dr. Watts principally relied, testified at the trial that the ingredients of these medicines in the quantities prescribed would not have the effect attributed to them, it appears that no reliance can be placed upon testimony based on their theory.

"The appellee strongly urges that there is a clear distinction between a contention that a medicine is recommended for the treatment of arthritis and a statement that a medicine will in some cases relieve the pain, swelling and limitation of movement associated with arthritis. We think we do not need to decide whether there is such distinction here as to make permissible the marketing of a product under the second representation which has been found not marketable under the first, because we think it clear beyond any question that the findings of the trial court that the Government had not carried its burden of proving that the Tri-Wonda medicines were not 'beneficial in a substantial number of cases in the relief of some symptoms of rheumatoid arthritis, rheumatism and bursitis, such as pain, soreness, the swelling of tissues around the joints, the loss of freedom of motion resulting from pain and soreness accompanying rheumatoid arthritis' was false and misleading is so 'against the great preponderance of the credible testimony that it does not reflect or represent the truth and right of the case.' *Sanders* v. *Leech, 5 Cir.*, 158 F. 2d 486, 487.

"We do not need to question the credibility of any of the witnesses. We assume that the trial court credited each of the appellee's witnesses with telling the truth. This does not, however, add any weight to testimony which, because of demonstrated lack of opportunity properly to base opinion, relegated such testimony to the class mentioned by this Court in the Hoxsey case as being contrary 'to all accepted scientific knowledge' and, therefore, not substantial.

"On the entire evidence we are left 'with the definite and firm conviction that a mistake has been committed.' *United States* v. *U.S. Gypsum Co.*, 333 U.S. 364, 395. The overwhelming weight of the evidence requires a conclusion that the representation that these medicines may relieve the pain or swelling or affect the limitation of movement accompanying rheumatoid arthritis is false and misleading.

"The trial court should, upon such evidence, have granted the injunction as prayed for and the court's failure to do so, as stated by us in the Hoxsey case, 'evidences an abuse of discretion.'

"REVERSED and REMANDED for further proceedings not inconsistent with this opinion."

CAMERON, *Circuit Judge*, Dissenting:

I.

"(a) This appeal by the United States is based upon 28 U.S.C.A. § 1291 investing this Court with jurisdiction of appeals from all final decisions of the district courts within the Fifth Circuit. The appellee filed and served a motion to dismiss the appeal upon the ground that the district court specifically retained jurisdiction of a portion of the claim sued on by appellant and that the judgment appealed from was not, therefore, a final judgment within the meaning of said statute. This Court ordered that the motion be argued along with submission of the appeal upon its merits, and that course was followed. In my opinion the motion of the appellee should be granted and the case should be remanded for such further hearing as the trial court may order, and the entry of a final judgment.

"It is necessary to understand that the court granted appellant an injunction exceedingly broad in its terms, as will appear from copy thereof set out in the margin.[3] The judgment did not grant appellee any injunction licensing her to introduce any drug at all into interstate commerce.

"The majority opinion states that the United States complained of the 'permissive part of the order,' which it quoted in paragraph 2 of the opinion. This statement was not made in the injunction portion of the judgment appealed from, but it was merely a recital in the preliminary paragraphs of the decree that the Government had failed to prove its claim with respect to whether the drugs were beneficial in a substantial number of cases in the relief of

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[3] ". . . and it is further ordered, adjudged and decreed.

"2. That Lela S. Wier . . . be and they are hereby perpetually enjoined and restrained under the provisions of 21 U.S.C. 332(a) from directly or indirectly introducing or causing to be introduced or delivering or causing to be delivered for introduction into interstate commerce, an article of drug known as 'Tri-Wonda,' 'Tri-Wonda Treatment,' 'Tri-Wonda No. 1,' 'Tri-Wonda No. 2,' 'Tri-Wonda No. 3,' or any other name, consisting of the following ingredients: [giving in detail the constituent chemicals] . . . or any similar drug, the labeling of which is false or misleading in any particular, and more specifically any such drug which is accompanied by the leaflets introduced in evidence as exhibits, entitled 'You May Now Profit by the Experience of Others,' 'Attention Arthritics,' the letters entitled 'Special Bulletin,' 'Dear Friend,' 'Thank you for your letter of recent date,' 'I am glad to tell you about my experience,' and testimonial letters from users of Tri-Wonda, or any other written, printed, or graphic matter, which represents or suggests, directly or indirectly, that the drugs, or either of them, or any similar drug, is a cure or adequate treatment for any form of arthritis or rheumatism, or that they are beneficial, or give relief or have any value for all forms of arthritis and rheumatism, or that they are beneficial, effective, or have any value in the cure, mitigation, relief, or treatment of muscular aches, pains, soreness, stiffness, and swellings which accompany gouty, tubercular, gonococcic arthritis or arthritis due to specific types of infection, sciatica or neuritis; and it is further—

"3. Ordered, adjudged and decreed that the defendant, Lela S. Wier, . . . be and they are hereby perpetually enjoined and restrained from directly or indirectly doing or causing to be done any of the following acts with respect to the aforesaid drug while held for sale after shipment in interstate commerce:

"(a) The use in the sale of the drug of any of the written, printed or graphic matter referred to in paragraph 2, or of any other written, printed, or graphic matter containing any of the claims or representations specified in paragraph 2.

"(b) Representing, in any manner, that the drug is useful in the prevention, treatment, mitigation, or cure of any disease, condition, or symptom, that is not stated and/or enumerated in the labeling thereof together with precise directions for effective and safe use in each such disease, symptom, or condition; and it is further—

"4. Ordered, adjudged and decreed that the defendant, Lela S. Wier, . . . be and they are hereby perpetually enjoined and restrained from directly or indirectly introducing or causing to be introduced or delivering or causing to be delivered for introduction into interstate commerce the aforesaid drug with labeling that does not include a statement and enumeration of all diseases, conditions and symptoms, for which the article is intended to be used, together with precise directions for effective and safe use in each such disease, condition, or sympton; . . . [Emphasis added.]

some symptoms of the diseases such as pain, soreness, swelling, constipation, etc.[4]

"Patently, in order to leave its finding No. 29 and its recital in the introductory portion of the order appealed from open for further testimony or action by either party, the court added, as the last paragraph (except that dealing with costs) of the injunctive order, the following:

> 6. Ordered, adjudged and decreed that the jurisdiction of this Court is retained for the purpose of enforcing this decree and for the purpose of granting such additional relief as may hereafter appear necessary or appropriate . . .

"This plain retention of jurisdiction by the court below, under the undisputed circumstances as set forth above, in my opinion, rendered the judgment unappealable. The general rule in such matters was thus stated by the Supreme Court in *Covington* v. *Covington First National Bank*, 1902, 185 U.S. 270 (syllabus):

> Matters within the pleadings in this case having been left undetermined by the court below, and the cause having been detained for the purpose of thereafter passing upon them, and for the entry of a further decree, the decree entered below was not final, and this Court is without jurisdiction to pass upon it.[5]

It is provided in Rule 54(c) F.R.C.P.:

> . . . every final judgment shall grant the relief to which the party in whose favor it is rendered is entitled . . .

Under this Rule and the language of § 1291 the case before us comes, in my opinion, precisely under our holdings in *King* v. *California*, *supra*.

(b) If appellant thought, as it now claims that the judgment of the court below was 'Ambiguous and Inconsistent' as it argues in the first point in its brief, it had the right under Rule 59(e) to serve 'A motion to alter or amend the judgment not later than ten days after entry of the judgment.' Having failed so to do, it cannot, in my opinion, attempt to put the court in error by a point raised in the first time on appeal. The judgment showed clearly on its face that it was not final and that jurisdiction was retained for further hearing on the very matter upon which appellant lays most stress. The right to appeal to this Court is statutory and the right does not, in my opinion, for the reasons set forth, exist.

II.

"I am unable to follow the majority in holding that the district judge was clearly erroneous in his holding that the drugs in question had been shown to be beneficial in the treatment of certain symptoms in a substantial number of people. This case was at issue in the early part of March 1954, and was tried at intervals when the district court could get around to it until its opinion was rendered October 22, 1958. The judgment appealed from was not entered until January 16, 1959. In nearly all instances the court heard the vast number of witnesses testify personally. The record is in nineteen volumes and contains 3,759 pages. Unless an appellate court is to read all of those pages, I do not see how it is in position to adjudge the findings of fact of the court, which heard all of the witnesses testify and all of the arguments and objections, were clearly erroneous under Rule 52 F.R.C.P.

"I do not think we should be overawed by the asserted high standing of some of the Government's witnesses. The United States is a rich litigant and is able to produce the best in the way of expert testimony. Without

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[4] This recital portion of the decree contained this further statement: "The Court did not adjudicate that the drug was beneficial, but only that the Government had failed to prove that it was not beneficial in the above respects . . ."

[5] To the same effect see City of Paducah 1. East Tennessee Telephone Co., 1913, 229 U.S. 476; 6 Moore's Federal Practice, 2d Ed. pp. 120 et seq.; King v. The California Co. et al., 5 Cir., 1955, 224 F. 2d 193, same case, 1956, 236 F. 2d 413. And cf. New Amsterdam Casualty Co. v. B. L. Jones & Co., 5 Cir., 1958, 254 F. 2d 917; Richards et al. v. Smith et al., 5 Cir., 1960, . . . F. 2d . . . .

reflection upon this character of testimony it can be said that all lawyers of experience know that experts generally stick pretty close to the line of the testimony of the litigant which employs them.

"Appellee's experts were general practitioners who were constantly called upon to treat people suffering from arthritis, rheumatism and the other maladies which the accused literature dealt with. Such doctors acquire necessarily a good working knowledge of palliatives which will give a measure of relief, even though probably temporary, to the symptoms attending those ailments. Certainly the Government does not desire that the average doctor be encouraged to sit idly by and permit people to suffer day after day because those in higher places have not discovered a cure for these common maladies. The trier of facts in this case had the right to consider their testimony and to give it such weight as he thought it deserved.

"The average man also has a pretty good idea of the symptoms which go with rheumatism and arthritis. Sufferers from them are legion and nobody, it seems to me, would deny that a witness may testify to the symptoms he has as the result of a malady diagnosed by a medical man as rheumatism or arthritis, and to testify that certain drugs have given him relief. That is all that the appellee's witnesses attempted to do, and that is the sole question involved in this appeal, that is, relief of certain symptoms to a substantial number of people suffering from the maladies listed in the judge's findings.

"The majority opinion does not attempt to analyze the testimony of the laymen who stated unequivocally that they were sufferers from these maladies and that their sufferings were alleviated by the use of the drugs in question. As a matter of interest, it will be found that twenty-two laymen did so testify. Excerpts from their testimony are set forth in the margin.[6] Even

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[6] Mrs. George Bosarge:

Q. "Referring to your lower spine, were you suffering pain there?"
A. "Terribly." . . .
Q. "Did you take those three medicines home with you?"
A. "I did."
Q. "Did you take them as prescribed?"
A. "I did."
Q. "Did you get any results?"
A. "I got pretty good results."
Q. "If you continued to take it tell what happened to your condition, whether you got better or worse."
A. "It did wonders for me—felt better than I have in years."
Q. "Do you feel worse or better?"
A. "Wonderful—It did not come back, not even in the spine."
Q. "It did not come back at all?"
A. "No."
Q. "You are free from pain today?"
A. "Yes."
Q. "Did you take any other medicines at that time?"
A. "No."

Mrs. Alice Guardia:

Q. "Will you tell the Court what you were suffering from at that time?"
A. "Pain in my right shoulder—could hardly move my arm. I went to Dr. Snelling for it."
Q. "What did he diagnose it as?"
A. "Arthritis."
Q. "This medicine, did you take it according to directions?"
A. "Near as possible I did."
Q. "Mrs. Guardia, what results, if any, did you get with reference to your pain . . .?"
A. "It left me."

Mrs. F. M. Tatum:

Q. "—did you have occasion to consult Dr. Snelling on account of some ailment you had in your joints?"
A. "Yes, I did."
Q. "At that time you were suffering in what part of your body?"
A. "My knee was paining me some."
Q. "Did Dr. Snelling give you any medicine for this?"
A. "Gave me this—(Reached for Tri-Wonda treatment which is exhibit in evidence)."
Q. "Did you take according to the prescription?"
A. "Yes."
Q. "What results, if any, did you get from it?"
A. "Helped me quite a bit—taken some time—maybe six weeks—don't know how long—after a while the pain ceased—quit taking it."
Q. "You definitely got your pain relieved as a result of it?"
A. "Yes, I did."

if, as indicated in a general way in the majority opinion, some inconsistencies developed or contradictions arose, the trial court had the duty of considering all of the testimony and arriving at the conclusion which to it was most consonant with the truth.

Mr. C. E. Cuevas:

Q. "Mr. Cuevas, at the time you came to see Dr. Snelling will you tell the Court how you were suffering?"
A. "All in my joints and my knuckles, knees and the back of my shoulder."
Q. "Did Dr. Snelling give you any medicine to try?
A. "That is right."
Q. "Did you take it the way the doctor told you to take it?"
A. "That is right."
Q. "Were you feeling any better when you returned to him?"
A. "That's right."
Q. "What was your condition, Mr. Cuevas, had it improved right along or not?"
A. "That is right. I was working and feeling better."
Q. "Are you free of pain in your joints now?"
A. "Yes, sir."

Mrs. W. E. Lizana:

Q. "Who is your regular physician at this time?"
A. "Dr. Snelling."
Q. "Where were you suffering?"
A. "In my arms and hands."
Q. "Were they giving you much pain or not?"
A. "Right smart, yes, sir."
Q. "What kind of medicine did Dr. Snelling ask you to try?"
A. "This Tri-Wonda."
Q. "Now, Mrs. Lizana, did you follow the doctor's directions and take the medicine?"
A. "Yes, I did."
Q. "Then tell the court whether it helped you or not?"
A. "It certainly did help me, as far as I know. My fingers couldn't bend. I couldn't do much, and I think it did me a lot of good."
Q. "Did it get you to where you could bend your fingers or not?"
A. "Yes."
Q. "Do you feel you did get very definite relief from the medicine?"
A. "I certainly did."
Q. "Did it relieve you from your pain?"
A. "Certainly did."

Walter V. Cross:

Q. "Will you tell the Court what caused the condition that you are in at the present time—what you have been suffering from?"
A. "Diabetes and rheumatoid arthritis."
Q. "At the time you took Tri-Wonda for the first time how were you suffering at that time with reference to pain in your joints or body?"
A. "Yes, I had a lot of pain in my arms, neck and back and some in my legs."
Q. "At this date are you in comparative comfort comparative to conditions before taking Tri-Wonda?"
A. "Oh, yes, definitely."

Mrs. Cennie Bell Anderson:

Q. ". . . how were you suffering, Mrs. Anderson? What parts of your body were involved in this pain?"
A. "It started in my left limb, foot, knee and in both thumbs."
Q. "Were the joints swollen or not?"
A. "They were swollen."
Q. "Before you began taking the Tri-Wonda, Mrs. Anderson, will you tell the Court whether or not the swelling and pain you had had affected your walking or not?"
A. "Indeed it had. I hurt getting up in the morning and would have to hold on to things and just slide my feet along."
Q. "After you had been taking Tri-Wonda for at least three weeks you began to walk better or not?"
A. "I would walk better and kept on improving. I do all my work now."

Mr. Edwin W. Whitehead:

Q. "At the time you consulted Dr. Atwood what was your condition? How were you suffering? What caused you to suffer?"
A. "I was hurting. The Doctor said it was arthritis. It was in my hips, back, legs from the knees on down—bad."
Q. "Swollen or not?"
A. "Some."
Q. "Referring to the pain, were you suffering much pain or not?"
A. "Yes, sir."
Q. ". . . you had been taking the Tri-Wonda treatment as the Doctor gave it to you and as prescribed on the bottle, taking it like it said on the bottle?"
A. "Yes."
Q. "At that time how did you feel . . ."
A. "I began to feel better."

"I think, too, that the majority is a little hard on appellee's experts, led doubtless by the passage quoted in the majority opinion from Professor Wigmore's work on Evidence. The majority well denominates what it quotes as 'Wigmore's comment.' The quotation shows that it is the author's personal opinion, and an examination of the cases cited will show both that none of them support the comment and that no case from any Federal court or any Mississippi court is cited in support of it.

"The Mississippi rule, which is the one applicable here, Rule 43(a) F.R.C.P.,[7] is thus stated in the first syllabus of *King* v. *King, et al*, S. Ct. Miss. 1931, 134 So. 827:

> To testify as an expert, witness need not be infallible or possess highest degree of skill; to testify as 'expert,' it is generally sufficient that witness possesses peculiar knowledge respecting matter involved not likely to be possessed by ordinary layman.[8]

"These holdings by the Supreme Court of Mississippi seem to be in line with the general rule as announced by American Jurisprudence, Vol. 20, Evidence, § 785, p. 659, where it is held that one may be competent to testify as an expert although he is not shown to be highly qualified to speak upon the subject, and that: 'It is usually held that any person whose profession or vocation deals with the subject in hand is entitled to be heard as an expert, leaving the value of his evidence to be tested by cross-examination and determined by the jury.'

"It is my opinion also that the majority is too strict in its attitude towards testimony of lay witnesses. All that is left in this case deals with the treatment of symptoms. The lay witnesses knew their own symptoms and they knew what happened to those symptoms when the accused drugs were administered. Those symptoms were admitted by all of the witnesses for the Government and the appellee to be symptoms of rheumatism, arthritis, etc. Under the general and the Mississippi law, the lay testimony admitted by the court below was competent.[9]

Q. "During all that time you continued to take this medicine?"
A. "Yes."
Q. "Tell the Court whether you continued to improve or not."
A. "Oh, yes, yes sir."
Q. "With reference to the swelling, what occurred in the joints that were affected, did it go down or not?"
A. "It went down."

The foregoing testimony is typical of that given by the twenty-two lay witnesses testifying for the defendant.

[7] "New York Life Insurance Co. v. Schletter et al., 5 Cir., 1953, 203 F. 2d 184; White et al. v. Holderby et al., 5 Cir., 1951, 192 F. 2d 722; and Petroleum Carrier Corp. v. Snyder, 5 Cir., 1947, 161 F. 2d 323.

[8] "See also Floyd v. State, S. Ct. Miss. 1933, 148 So. 226, 231, where the Supreme Court reversed the judgment of a trial court in part because the court below refused to let a doctor give his professional opinion that a second blow could not have been self-inflicted by a person who had already been struck one blow. The Supreme Court stated: 'It is true that Dr. Crisler may have had more experience as a surgeon, or higher training as a student, but Dr. Sigrest had been trained as a general practitioner and had had 30 years' experience. . . . [We think] that a physician who had made the study of the human body a profession, and who had considerable practice, could be called an expert.'

"And in J. W. Sanders Cotton Mill v. Moody, S. Ct. Miss., 1940, 195 So. 683, 689, the court held that a chiropodist could testify as an expert in the interpretation of X-ray pictures and respecting injuries to the foot generally even though he had not had the training ordinarily required of a physician.

"And in Wallace v. State, 1948, 35 So. 2d 703, 704, the Supreme Court of Mississippi quoted 20 Am. Jur. page 692 in its statement that: 'Any person who has, by sufficient experience, acquired adequate knowledge of X-rays and their interpretation may qualify as a witness.' The court repeated also that 'It is sufficient if he possesses peculiar knowledge, wisdom, or information regarding the subject matter, acquired by study, investigation, observation, experience, or practice, not possessed by the ordinary layman or inexperienced person.'"

[9] The Supreme Court of Mississippi in Pearl River Valley R. Co. v. Moody, 1937, 171 So. 769, sanctioned the receipt of testimony given by a lay witness, in an action to recover for injuries sustained, as to his continuous pain and suffering. Also, in Illinois Cent. R. Co. et al. v. William, 1926, 110 So. 511, it was held by the Mississippi Supreme Court that an instruction to the jury was correct which permitted the consideration of testimony given concerning the physical pain and suffering endured by a party, holding that such testimony was competent.

This law as stated by the courts of Mississippi also appears to be in accord with the general law, as it is given in 32 C.J.S., Evidence, § 513, p. 171: "While a nonexpert or

"What the majority really holds here is that the trial court drew the wrong conclusions from the competent testimony. I cannot agree with that holding. I think there was ample evidence to support the trial court's findings and conclusions as to the facts.

"Surely this case is not ruled by *United States* v. *Hoxsey Cancer Clinic, et al.*, 5 Cir., 1952, 198 F. 2d 273. We held that the literature used in *Hoxsey* represented that the drugs involved would cure some internal cancers and relieve other internal cancers.[10] In the case before us the trial court specifically enjoined, as will appear from the quotation in Note 3 *supra*, the use of any written or printed matter 'which represents or suggests, directly or indirectly, that the drugs, or either of them, or any similar drug, is a cure or adequate treatment for any form of arthritis or rheumatism. . . .' Appellee did not appeal from that portion of the judgment, claiming that she had made no such representations. The case before us involves, not any representations concerning cures, but representations relating alone to relief from some of the symptoms or 'miseries' attendant upon the maladies under consideration.

"While it is my opinion that the merits should not be reached and that the case ought, on the motion to dismiss the appeal, to be sent back to the trial court for further handling, I think that the majority opinion fails to demonstrate that the findings and conclusions of the trial court are clearly erroneous.

III.

"Finally, I think it is unwise, in a case such as this, to substitute our judgment for that of the district judge in refusing or granting injunctive relief in connection with the enforcement of statutes such as that before us. The formulae here involved had been originated about 1900 by Reverend H. A. Hall who seems to have marketed them successfully until about 1938 when he stipulated with the United States Post Office Department to discontinue using the mail in connection with them, confining his marketing thereafter to the State of Florida. The appellee's connection with them began in 1950 when, being a sufferer from rheumatoid arthritis, she first took the Hall products and attributed her improvement to them. The development of the sale of the products under the name of 'Tri-Wonda' followed that experience.

"Officials of the Government began investigating the appellee in 1951 and various dealings, most of them controversial, have been had between them from that date until the filing and disposition of this civil action.

"The trial court lived with the whole controversy intimately for a period of about four years, and the conclusions reached by him were based upon a 'feel' of the case we could not possibly acquire. I do not think we should disturb a finding and judgment entered by such an able, conscientious and experienced trial judge as the one who sat on this case without a clear showing of abuse of discretion.

"That has been the policy of this Court for many years, *Walling* v. *Florida Hardware Co.*, 1944, 142 F. 2d 444; *Mitchell* v. *Hodges Contracting Co., et al.*,

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lay witness may not give expert testimony as to his physical condition, he may state simple inferences drawn from his conscious subjective sensations concerning such condition:" and in 20 Am. Jur., Evidence, § 859, p. 720; "One, not an expert, may testify as to the state of his own health."

[10] The following quotation, made up of several disconnected statements in the long opinion, demonstrates that this Court construed the representations there condemned as assuring those reading it that the drugs would cure internal cancer:

[Page 276] "For the purpose of this decision and in determining the truth of such representations, we will accept the more restricted position, to which the Government is driven, that the precise extent of successful cures is immaterial since, it is contended, that the representation that any cure can be effected by use of the medicine is false and misleading. . . . It is difficult to imagine that one thinking himself inflicted with the dire disease of cancer and reading and considering the references to these listed patients, and the testimony there set forth, . . . would reach any other conclusion than that the persons listed were cured of cancer by the Hoxsey drugs.

[Page 280] ". . . Our consideration of the record and the nature of the issues involved has led to the firm conclusion that the trial Court's findings of fact that the representations in the labeling were neither false nor misleading, and that the brownish-black and pink-colored medicines were efficacious in the cure of cancer in man are clearly erroneous. . . .

[Page 281] "Furthermore, as we have held, the overwhelming weight of the credible evidence requires a conclusion that the representation that the Hoxsey liquid medicines are efficacious in the cure of cancer is likewise false and misleading."

1956, 238 F. 2d 380, 381; *Mitchell* v. *Bland*, 1957, 241 F. 2d 808, 811; *Mitchell* v. *Strickland Transportation Co.*, 267 F. 2d 821; and our decisions have been based upon Supreme Court decisions.[11]

"In *Mitchell* v. *Lublin McGaughy and Asso.*, 1959, 358 U.S. 207, 215, the Supreme Court referred to our decision in *Bland supra* at page 810, from which we quote:

> But we do not consider these considerations of controlling importance. Even assuming appellant's contentions to be sound in both instances, the Court would have been justified in either granting or denying injunctive relief under the broad discretion lodged in it by accepted equitable principles. . . .
>
> The trial Court evidently reached the conclusion that more could be accomplished towards enforcement of the law and towards bringing appellant into cooperative conformity with its provisions by withholding the drastic remedy of injunction than by using it. . . .
>
> The problem before the Court below did not involve litigation between two private individuals only; it related primarily to the business of the public and the public interest was entitled to primary consideration. . . .
>
> The same ideas were expressed by the Supreme Court in dealing with the enforcement of the Emergency Price Control Act, . . . in a case wherein the problem presented was quite similar to that before the Court in this case. Hecht involved a prayer for injunctive relief where a spot check of seven out of more than one hundred departments of a large store revealed four thousand five hundred violations of the law. After a full hearing, the District Judge denied injunction pursuant to its general equity powers: "In a case such as this an injunction should not issue unless thereby better compliance with law may be enforced . . . and in my judgment an injunction would not be in the public interest . . ." The Court of Appeals for the District of Columbia reversed on the theory that the District Judge had given too wide a sweep to traditional equity powers. The Supreme Court granted certiorari and reversed the action of the Court of Appeals approving what the District Court had done . . .

"I think the case before us presents a much stronger appeal for approving the district judge's use of his discretion than any of those mentioned.

"I think that the recognition by appellate courts that discretion belongs uniquely to the district courts is of very great importance and, for that reason, I have felt constrained to set down at some length the grounds of my dissent in this case."

On 2–13–61, the United States District Court for the Southern District of Mississippi entered a decree of permanent injunction enjoining the defendant from:

(a) Directly or indirectly introducing or causing to be introduced into interstate commerce, an article of drug, known as "Tri-Wonda," "*Tri-Wonda Treatment*," "Tri-Wonda No. 1," "Tri-Wonda No. 2," or "Tri-Wonda No. 3," or any similar drug, the labeling of which, within the meaning of 502(a) of the Act is false or misleading in any particular, and more specifically any such drug which is accompanied by the leaflets entitled "You May Now Profit by the Experience of Others," "Attention Arthritics," the letters entitled "Special Bulletin," "Dear Friend," "Thank you for your letter of recent date," "I am glad to tell you about my experience," and testimonial letters from users of "Tri-Wonda," or any other written, printed, or graphic matter, which represents or suggests, directly or indirectly, that the drugs, or either of them, or any similar drug, is a cure, or an adequate treatment, or is useful for treating any form of arthritis or rheumatism, or that they are beneficial, or give

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[11] Such as Texas v. Pullman Co., 1941, 312 U.S. 491; and Hecht Co. v. Bowles, 1944, 321 U.S. 321.

relief, or have any value for all forms of arthritis and rheumatism, or that they are beneficial, effective, or have any value in the cure, mitigation, relief, or treatment of muscular aches, pains, soreness, stiffness, and swellings or any other symptoms which may accompany any form of arthritis or related diseases;

(b) Directly or indirectly doing or causing to be done any act with respect to any such drug, while held for sale after shipment in interstate commerce, which results in the drug being misbranded within the meaning of 502(a) of the Act, specifically including, but not limited to the following acts while the drug is held for sale after shipment in interstate commerce:

1. The use in the sale of the drug of any of the above written, printed or graphic matter, or of any other written, printed, or graphic matter containing any of the above claims or representations;
2. Representing in any manner, that the drug is useful in the prevention, treatment, mitigation, or cure of any disease, condition, or symptom, that is not stated and/or enumerated in the labeling of the drug together with precise directions for effective and safe use in each such disease, symptom or condition; and

(c) Directly or indirectly introducing or causing to be introduced into interstate commerce, any such drug with labeling that does not include a statement and enumeration of all diseases, conditions, and symptoms, for which the article is intended to be used together with precise directions for effective and safe use in each such disease, condition, or symptom.

The decree of injunction further ordered that defendant should give notice of the provisions of this decree to certain of her associates; that the effective date of the injunction should be 3–13–61; that the defendant's application for a further stay pending appeal was denied; and that all costs of court were taxed against the defendant.

Subsequently, on 3–23–61, the United States District Court for the Southern District of Mississippi overruled the defendant's motion for a new trial and, on 3–25–61, the court overruled the defendant's motion for a stay of the final injunction. The defendant appealed the latter ruling, and the United States Court of Appeals for the Fifth Circuit dismissed this appeal. On 10–10–61, the defendant's motion to retax costs was granted in part in that the defendant was excepted from payment of the costs of multilithing the transcript of the record of the trial.

6552. Various drugs. (Inj. No. 400.)

COMPLAINT FOR INJUNCTION FILED: On 3–20–61, S. Dist. Calif., against Hamid Bey, t/a Bey Vita Products Co. and Coptic Fellowship of America, Los Angeles, Calif.

NATURE OF BUSINESS: The defendant was engaged in the business of promoting, through lectures and through the dissemination of letters, and other written, printed, and graphic matter, the interstate sale of the following articles: *Bey Saffto* composed of unsaturated fatty acids derived from safflower oil, and vitamin B_6; *Bey VA* composed of vitamin A–from lemon grass oil; *Bey Natural VC* composed of vitamin C–from rose hips with rutin; *Bey VE* composed of alpha-tocopherol; *Ro-Qee-Jel capsules* composed of royal jelly, vitamin B_1, vitamin B_{12}; *Bey Vita Natur-Cal* composed of calcium, phosphorus, and vitamin D; *Bey Vita RG Soya Lecithin* composed of oil-free lecithin derived from soya bean oil; *Bey Vita yeast tablets* composed of yeast containing vitamins B_1 and B_2; *Bey Proto-X* composed of amino acids with vitamins B_{12}

and B_1; and *Calpans* composed of brewer's yeast, calcium pantothenate, and vitamin B_1.

CHARGE: The complaint alleged that the defendant caused the above-named articles to be shipped to various cities throughout the country where he gave lectures on health subjects and made therapeutic claims for the articles; that on the basis of such claims, the audience was induced to purchase the articles which were available for sale at the lectures; and that the defendant also caused the above articles to become misbranded under 502(f)(1), when shipped and while held for sale, because the labeling of such articles failed to bear adequate directions for use since it did not declare the conditions and purposes for which the defendant orally represented and suggested that the articles were effective, namely: *Bey Saffto* for change of life, overweight, dry skin conditions, itchy skin, skin breaks, to oil skin, to feed glands, to remove wrinkles, to dissolve fat, and to remove body impurities; *Bey VA* for bad eyesight, eye sensitivity, cataracts, glaucoma, poor blood, arthritis, liver ailments, to neutralize excessive mucous in membranes, and to purify blood stream; *Bey Natural VC* for infected blood stream, kidney infection, high blood pressure, capillary fragility, impaired circulation, bleeding, stomach ulcers, varicose veins, mucous in sinus, ears, and membranes, anemia, arthritis, to coagulate blood in skin cuts, and to eliminate mucous from membranes; *Bey VE* for cataracts, glaucoma, heart trouble, muscular degeneration, skin breaks, arthritis, to renew muscle tone, and to sober up from drunkenness; *Ro-Qee-Jel capsules* for cataracts, glaucoma, heart trouble, muscular degeneration, skin breaks, arthritis, to renew muscle tone, to sober up from drunkenness, and liver conditions; *Bey Vita Natur-Cal* for brittle nails, brittle hair, varicose veins, arthritis, change of life in women, to quiet and relax, to induce sleep, and to build blood; *Bey Vita RG Soya Lecithin* for inflammation of lining of veins, brittle veins, brittle capillaries, brittle blood vessels, impaired circulation, sluggish blood, anemia, abnormal heart and blood pressure, obesity, liver trouble, kidney trouble, blood trouble, to dissolve cholesterol in blood, blood stream, and liver, and to provide food for brain and nerves; *Bey Vita yeast tablets* for poor digestion, obesity, duodenal ulcers, intestinal ulcers, impaired nerves, and impaired muscles; *Bey Proto-X* for diabetes, stomach ulcers, and arthritis; and *Calpans* for liver conditions, to promote growth in children, and to restore original color to hair.

The complaint alleged also that, should the articles bear labeling stating such conditions and purposes, the articles would then be misbranded within the meaning of 502(a) since such labeling would be false and misleading in that the articles would not be effective for such conditions and purposes.

DISPOSITION: On 3–27–61, the defendant having consented, the court entered a decree of permanent injunction enjoining the defendant against commission of the acts complained of.

6553. Tri-Sulfa tablets. (F.D.C. No. 45511. S. No. 61–029 R.)

QUANTITY: 38 btls. at St. Joseph, Mo., in possession of United Pharmacal Co., Inc.

SHIPPED: 12–27–60, from New Rochelle, N.Y.

LABEL IN PART: (Btl.) "100 Tablets UPCO Tri-Sulfa Tablets Formulated for United Pharmacal Co. * * * Each tablet contains: Sulfadiazine 2½ grains Sulfamerazine 2½ grains Sulfathiazole 2½ grains Usual Dose * * * Warning * * * Caution."

RESULTS OF INVESTIGATION: The article was shipped in unlabeled bottles as described above, and after receipt at St. Joseph, Mo., was labeled by the dealer.

LIBELED: On or about 3–16–61, W. Dist. Mo.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement since it was a prescription drug labeled for human use and it was not in the possession of a person or firm regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs for human use.

DISPOSITION: 5–5–61. Default—destruction.

6554. Figurette protein tablets. (F.D.C. No. 43950. S. No. 56–630 P.)

QUANTITY: 10 cases, 12 btls. each (5 cases of which contained mint-flavored tablets and 5 cases, cherry-flavored tablets), at Atlanta, Ga., in the possession of Figurette, Inc.

SHIPPED: 4–7–59, from Cleveland, Ohio, by Don Saunders, t/a Destiny Enterprises.

LABEL IN PART: "Figurette Protein 200 Tablets Mint Flavor [or "Cherry Flavor"] Distributed by Destiny Enterprises, 708 Frankfort Ave., Cleveland, Ohio Each tablet contains 76% Protein from Soya in readily digestible form. 16% Carbohydrate (Glucose) Glycerin, Tricalcium Phosphate, Magnesium Stearate and Bentonite and Sweetened with 6.5 Mg. Cyclamate Sodium and 0.65 mg. Saccharin Sodium * * * 3 calories per tablet."

LIBELED: 12–4–59, N. Dist. Ga.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article, by supplying protein, was an excellent source of energy and was an essential factor in tissue repair and maintenance of nitrogen balance, that the article was an effective weight reducing aid in "slenderizing studios," and that the article was an effective appetite appeaser; and 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, in building up healthy muscles, burning up fat, and reducing weight without need of a special reducing diet, which representations were made orally by a sales representative of the dealer firm.

DISPOSITION: On 1–11–60, Destiny Enterprises, Inc., filed a claim to the article and an answer denying that the article was misbranded. The Government served written interrogatories on the claimant. The claimant failed to file answers to the written interrogatories and the court, upon the motion of the Government, rendered a judgment of condemnation by default on 2–23–61, together with an order directing the destruction of the article.

6555. Trapper's Herbal Preparations. (F.D.C. No. 45335. S. Nos. 44–296/7 R, 44–299/300 R.)

QUANTITY: 30 15-gram pkgs. and 53 4-gram pkgs. of *Formula #1;* 22 1-oz. vials of *Formula #3* and 27 1-oz. vials of *Formula #4*, at Spokane, Wash.

SHIPPED: Between the approximate dates of 6–1–60 and 6–15–60, from Boise, Idaho, by Baker's International Distributors.

LABEL IN PART: (Pkg.) "Trapper's Herbal Preparation Formula No. 1 * * * Manufactured & packed by Cecil J. Cardwell Trapper's Laboratory–921

Leadville–Boise, Idaho Bakers–International Distributors of Trapper's Herb Products, P.O. Box 736, Boise, Idaho" and (vial) "Trapper's Herbal Ointment Formula No. 3 * * * Ingredients: Carbolated Petroleum Jelly [or "Amber Petrolatum"] * * * Marigold Flowers, Balsam Pitch, Turpentine, Mullen, Bees Wax, Cedar Berries" and "Trapper's Herbal Ointment Formula No. 4 * * * Active Ingredients: Carbolated Petroleum Jelly * * * Marigold Flowers, Balsam Pitch, Turpentine, Mullen, Bees Wax, Cedar Berries."

ACCOMPANYING LABELING: Leaflets and folders entitled "Trapper's Herbal Preparations" and folders entitled "Trapper's Herb Products."

LIBELED: 1–17–61, E. Dist. Wash.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the *Formula #1* was adequate and effective as a treatment for sinus, sinus headache, colds, nasal drip, and congested nasal passages, hay fever and asthma; that the *Formula #3* was an adequate and effective treatment for hard-to-heal sores, bed sores, cold sores, externally caused skin irritation such as eczema, and chapped or detergent burns, hemorrhoids, dryness and sores of nasal passages, and that the *Formula #3* would "help nature rebuild diseased tissues"; and that the *Formula #4* was an adequate and effective treatment for burns, scalds, sunburn, cuts, abrasions, poison oak, detergent burns of the hands and arms, chapped skin and lips, eczema, poison ivy, and that the *Formula #4* would "help nature rebuild diseased tissues"; and 502(f)(2)—the labeling of the *Formula #3* failed to bear a warning that in case of rectal bleeding, a physician should be consulted promptly.

DISPOSITION: 3–22–61. Default—destruction.

6556. Mineralpar tablets. (F.D.C. No. 45463. S. No. 50–209 R.)

QUANTITY: 1 unlabeled ctn. containing 10,000 tablets, and 15 labeled boxes each containing 125 tablets, at Denver, Colo., in possession of A. W. Blaine; and 50 lbs. of bulk raw humus and 20,000 unlabeled tablets, at Denver, Colo., in possession of Larre Laboratories, Inc.

SHIPPED: The article "*Mineralpar*" was prepared by the dealer, A. W. Blaine, from bulk humus which he personally dug in July 1958, from the soil, on land located at Panaca, Lincoln County, Nev. The material was then transported by the dealer to Denver, Colo., where it was pulverized. The pulverized material was delivered by the dealer to Larre Laboratories, Inc., where it was formed into tablets. A number of the tablets were carried by the dealer in bulk drums to his residence in Denver, Colo., where he placed the tablets in boxes.

LABEL IN PART: (Box) "Approximately 7 Grain Each * * * MINERALPAR Made By Nature Contains a natural Mineral taken from a natural concentrated mineral deposit. Analysis shows it to be a complex association of Humas matter combined with silicates of Calcium, Potassium, Sodium and Alumina, probably resulting from the decomposition of organic substances such as Chlorophyl and other vegetable compounds. * * * Distributed by Mineralpar Box 53 Cheyenne, Wyoming * * * sold only as a Mineral Supplement To Your Diet."

ACCOMPANYING LABELING: Leaflets entitled "How to Use Mineralpar" and "For All-Around Health Protection"; pamphlets entitled "Modern Miracle Men"; an undetermined number of "*Mineralpar*" labels and labeled retail boxes; and a number of copies of customer-signed invoices, given to customers

at the time of sale, on which were listed the diseases, conditions, and symptoms for which the article was sold.

LIBELED: 2–7–61, Dist. Colo.

CHARGE: 502(a)—(article in bulk and as repacked)—while held for sale, the accompanying leaflet entitled "How to Use Mineralpar" contained false and misleading representations that the article was an adequate and effective treatment for "disorder or ailment"; the accompanying pamphlet entitled "Modern Miracle Men" contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of diseases, disorder, suffering and shortened life, stupidity in children, rickets, bone deformities, bad teeth, nervous disorder, reduced resistance to disease, fatigue, behavior disturbances, such as incorrigibility, assaultiveness, and nonadaptability, affectations of the nose and throat, swollen glands, enlarged or diseased tonsils, defective vision, round shoulders, bowed legs, anemia, goiter, nerve function, nerve stability, nerve cell building, increased human death rate due to heart disease, deformities and arthritis, and would result in physical, moral, and mental fitness; the accompanying leaflet entitled "For All-Around Health Protection" contained false and misleading representations that use of the article would prevent vitamin deficiency with resultant prevention of disorder and disease; and the accompanying invoices given to customers at the time of sale contained false and misleading representations that the article was an adequate and effective treatment for general body-building and conditioning, diabetes, nervousness, sleeplessness, fatigue, leg ulcers, hay fever, and to prevent colds; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended.

The article also was alleged to be misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 3–31–61. Default—destruction.

6557. Vi-Aspirin tablets. (F.D.C. No. 45097. S. No. 20–491 R.)

QUANTITY: 91 100-tablet cartoned btls. and 275 25-tablet cartoned btls. at Detroit, Mich.

SHIPPED: 2–3–60, from Naperville, Ill., by Amurol Products Co.

LABEL IN PART: (Btl. and ctn.) "Amurol * * * Vi-Aspirin Each tablet contains 5 grs. Aspirin 30 Mg. Vitamin C For The Relief of Pain Associated With Headaches Colds Amurol Products Company, Naperville, Illinois * * * Vitamin C Added To Help Increase Resistance To Infection."

ACCOMPANYING LABELING: (Leaflet in ctn.) "Amurol Vi-Aspirin."

LIBELED: 11–25–60, E. Dist. Mich.

CHARGE: 502(a)—when shipped, the name "Vi-Aspirin" and references in the labeling to vitamin C, and the statement on the label "Vitamin C added to help increase resistance to infection" were false and misleading as applied to a product whose only therapeutic value was that of an analgesic and antipyretic; and 502(f)(2)—the article was offered for the relief of minor pains of arthritis, rheumatism, and related ailments, and for minor throat irritations, and its labeling failed to bear a warning that if pain persisted for more than 10 days or redness was present, or in conditions affecting children under 12 years of age, a physician should be consulted immediately; and that if severe or persistent sore throat, or sore throat accompanied by high fever, or

headache, nausea, or vomiting was present, a physician should be consulted immediately.

DISPOSITION: 3–23–61. Default—destruction.

6558. **Think-Eze tablets.** (F.D.C. No. 45272. S. No. 17–684 R.)

QUANTITY: 73 100-tablet btls., 446 48–tablet btls., 394 24-tablet btls., and 287 8-tablet pkgs., at Denver, Colo.

SHIPPED: On 8–2–60 and dates subsequent thereto, from Huntington Park, Calif., by Retail Distributors Service, Inc.

LABEL IN PART: (Btl. and pkg.) "Think-Eze has a Tranquilizer action–An Aid To Relieve Nervous Tensions and help to obtain Normal Steady Nerves * * * Aldan Distributors, Inc., New York, N.Y. Long Beach, Calif. * * * Each Think-Eze tablet contains: Thiamine HCl (Vit. B–1) 1 mg. Niacinamide 5 mg. Ammonium and Sodium Bromides 4.75 gr. blended in a specially formulated and prepared inert base containing: Salicylamide, Glycyrrhiza Extract, Valerian Root, Pleurisy Root, Humulus Lupulus, Extract of Jamaica Dogwood."

ACCOMPANYING LABELING: Window banners reading in part "Think-Eze Tablets . . . With * * * Tranquilizer Action" and a number of large and small display units.

LIBELED: 12–7–60, Dist. Colo.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for nervous tensions, emotionally upset stomach, mental depression, and nerve-racking headaches; 502(a)—the statement "Tranquilizer" appearing on the labels and in the accompanying labeling when read in the setting in which presented, represented and suggested that the article would produce all of the effects capable of being produced by a commonly accepted true "tranquilizer" drug, whereas, the article was not a "tranquilizer" drug and would not produce all of the effects capable of being produced by a true "tranquilizer," and it would not provide the tranquilizing benefits claimed for it; 502(c)—the ingredient information required under 502(e)(2) and the warnings required by 502(f)(2) to appear in the labeling of the article were not prominently placed on the label and labeling with such conspicuousness, as compared with other statements on the label and labeling, as to render such information and warnings likely to be read and understood by the ordinary individual under customary conditions of purchase and sale; and 502(f)(2)—the labeling of the article failed to warn that it should not be given to children, and that its use should be discontinued if nervous symptoms persisted, recurred frequently, or were unusual.

DISPOSITION: 3–20–61. Default—destruction.

6559. **Analjel.** (F.D.C. No. 45189. S. No. 20–039 R.)

QUANTITY: 396 btls. at Lorain, Ohio.

SHIPPED: 8–16–60, from Pittsburgh, Pa., by the Federal Rice Drug Co.

LABEL IN PART: (Btl.) "Analjel a Nongreasy Analgesic Balm 2 Oz. Detroit First Aid Co., Detroit, Michigan Contents: Methyl Salicylate, Natural Menthol, Camphor, Oil of Peppermint."

LIBELED: 1–3–61, N. Dist. Ohio.

CHARGE: 502(a)—when shipped, the bottle label contained false and misleading representations that the article was an adequate and effective treatment

for rheumatism, neuritis, sprains, colds, etc.; and 502(f)(2)—the labeling failed to warn that the article should not be used otherwise than as directed; that it should be kept out of the reach of children; and that its use should be discontinued if excessive irritation of the skin developed.

DISPOSITION: 2–8–61. Default—destruction.

6560. Figurama device. (F.D.C. No. 42969. S. No. 27–707 P.)

QUANTITY: 20 devices individually cartoned at St. Paul and Minneapolis, Minn.

SHIPPED: 1–27–59 and 1–29–59, from Milford, Conn.

LABEL IN PART: "Tempulse Figurama By Streamform Corp., New York, N.Y."

RESULTS OF INVESTIGATION: Examination indicated that the device was a streamlined box-shaped housing containing an electric motor which provided vibrating and/or oscillating action to two pads located atop the housing. The pads contained a controlled heating element; and detachable tubular padded extensions converted the housing to a table-type device.

LIBELED: 4–7–59, Dist. Minn.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use as a treatment for relieving polio or any disease of that type; reducing; easing an incurable disease; relieving arthritis, bursitis, rheumatism, and neuritis; increasing blood circulation to all parts of the body to keep one from becoming sick, losing hair, getting wrinkles, or having high blood pressure; improving posture and firming the body tissues; banishing nervous tension; as a "help for everything"; spot reducing and taking off inches; which were the conditions and purposes for which it was offered in oral statements made by a sales representative in Minneapolis, Minn., on 2–2–59 and 2–3–59.

DISPOSITION: In May 1959, the Streamform Corp. filed a claim to the articles. Thereafter, the action was removed at the claimant's motion to the United States District Court of New Jersey where an answer was filed by the claimant denying that the articles were misbranded. After further litigation including the submission of written interrogatories by the Government, the submission of answers by the claimant, a motion by the Government to compel further and more complete answers, and an order of the court that the claimants submit further and more complete answers, a consent decree of condemnation was filed on 10–20–60. The claimant failed to file the bond required by the consent decree for the release of the goods to the claimant for relabeling under Government supervision. A default decree was filed on 1–27–61, and the devices were ordered to be turned over to the Department of Health, Education, and Welfare, Food and Drug Administration, Minneapolis, Minn., for exhibit purposes.

6561. Ultra-Sonic device. (F.D.C. No. 44591. S. No. 43–699 R.)

QUANTITY: 1 device at Great Falls, Mont., in possession of Elizabeth Webb Hill.

SHIPPED: 8–14–59, from Los Angeles, Calif., by Ace Medical Instrument Co.

LABEL IN PART: (Metal plate on device) "Ace Ultra-Sonic * * * Manufactured by Electronics Instrument Co., Los Angeles, Calif."

ACCOMPANYING LABELING: Leaflets entitled "Operating Instructions" and "Ace Ultra-Sonic Deluxe Model."

RESULTS OF INVESTIGATION: Examination indicated the device to be an electronic device producing ultrasound energy at 960,000 cycles per second through a 10 square centimeter sound head. The instrument cabinets con-

tained an oscillator and power supply. The front panel contained a timer, intensity control, and power output meter.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, the treatment of disease or abnormal conditions of the nerves, head, neck, shoulders, thoracic region, lumbosacral region, arteries, joints, upper extremity, and lower extremity; 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use for any condition and it was not exempt under the provisions of Regulation 21 CFR 1.106(d) from bearing adequate directions for use since it was a prescription device sold to and in possession of a person not entitled to use such a device.

DISPOSITION: 10–20–60. Consent—claimed by W. M. Jacobson, t/a Ace Medical Instrument Co. and relabeled.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

6562. Verutal-T tablets. (Inj. No. 335. S. No. 39–980 P.)

PETITION FILED: 11–5–59, N. Dist. N.Y., against Rand Pharmaceutical Co., Inc., Rensselaer, N.Y., to show cause why it should not be punished for criminal contempt for violation of the permanent injunction which had been entered against the Delmar Pharmacal Corp., on 7–22–58 (see preceding notice of judgment No. 6546).

LABEL IN PART: "Verutal-T * * * Each tablet contains: Veratrum Viride 100 mg. Rutin 10 mg. Reserpine .075 mg. Mannitol Hexanitrate ½ gr."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 22 percent of the labeled amount of mannitol hexanitrate and 66 percent of the declared amount of rutin.

CHARGE: The petition alleged that the Rand Pharmaceutical Co., Inc., on 10–11–58, caused to be introduced and delivered for introduction into interstate commerce at Rensselaer, N.Y., for delivery to South San Francisco, Calif., a number of bottles of "Verutal-T" which were adulterated within the meaning of 501(c) in that the strength of the drug differed from that which it purported and was represented to possess.

It was alleged further that the Rand Pharmaceutical Co., Inc., had been and was affiliated with the Delmar Pharmacal Corp. in the distribution of drugs in interstate commerce, and that Rand Pharmaceutical Co., Inc., had violated the injunction by causing the adulterated drug to be introduced and delivered for introduction into interstate commerce while the Delmar Pharmacal Corp. continued to operate its plant without complying with the following requirements of the injunction:

(a) that sufficient qualified and experienced personnel be employed to properly operate the plant;
(b) that incoming raw materials be analyzed;
(c) that all finished products be analyzed; and
(d) that a control system be installed which a representative of the U.S. Food and Drug Administration had determined to be adequate and which embodied all of the safeguards listed in the injunction as necessary to good pharmaceutical manufacturing practice.

*See also No. 6546.

DISPOSITION: On 11–5–59, the order to show cause was issued. Thereafter, the defendant pled guilty to the charge of violating the injunction and, on 3–21–60, the court fined the defendant $1,000.

6563. **Palivite.** (F.D.C. No. 45382. S. No. 26–602 R.)

QUANTITY: 40 cartoned vials at Los Angeles, Calif.

SHIPPED: 5–26–59, from Detroit, Mich.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 50 percent of the declared amount of vitamin B_{12} activity.

LIBELED: 1–9–61, S. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Each Ml contains not less than: Vitamin B_{12} Crystalline 50 mcg * * * 0.5% Liver Injection (B_{12} Activity Per Ml Equivalent to 10 mcg of Cyanocobalamin)" was false and misleading as applied to an article containing less than the declared amount of vitamin B_{12}.

DISPOSITION: 2–2–61. Default—destruction.

6564. **Geralix syrup.** (F.D.C. No. 45338. S. No. 5–431 R.)

QUANTITY: 19 1-gal. ctnd. btls. at Baltimore, Md.

SHIPPED: 10–26–60, from Maplewood, Mo., by Na-Spra, Inc.

LABEL IN PART: (Btl. and ctn.) "Geralix Vitamin-Mineral Syrup A Dietary Supplement for Young and Old Each Tablespoonful Provides Methamphetamine Hydrochloride 1.0 mg. Choline Cihydrogen Citrate 250.0 mg. Inositol 50.0 mg. Vitamin B–1 (Thiamine Hydrochloride) 5.0 mg. Vitamin B–2 (Riboflavin) 3.0 mg. Vitamin B–6 (Pyridoxine Hydrochloride) 0.2 mg. Vitamin B–12 5.0 mcg. Niacinamide 10.0 mg. Calcium Pantothenate 3.0 mg. Iron from Ferric Ammonium Citrate 10.0 mg. Copper from Copper Sulfate 1.0 mg. Calcium from Calcium Glycerophosphate 20.0 mg. Phosphorus from Calcium Glycerophosphate 15.0 mg. * * * Dosage * * * Caution * * * Control No. A4088 Distributed by Baare Drug Company, Baltimore, Md."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 50 percent of the declared amount of vitamin B_{12}.

LIBELED: On or about 1–11–61, Dist. Md.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statement "Vitamin B–12 5.0 mcg." was false and misleading as applied to a product containing less than the declared amount of vitamin B_{12}, and the label contained statements which represented and suggested that the article was a special dietary food, which statements were false and misleading since the article was in fact a potent prescription drug, namely, a preparation of methamphetamine hydrochloride.

DISPOSITION: 2–17–61. Default—destruction.

6565. **Juniplex and liver injection.** (F.D.C. No. 44560. S. Nos. 62–210 P, 62–212 P.)

QUANTITY: 72 btls. of *Juniplex*, and 13 vials of *liver injection*, at San Francisco, Calif.

SHIPPED: Between 5–5–59 and 12–8–59, from Chicago, Ill.

LABEL IN PART: (Btl.) "Syrup No. 42 8 Fl. Ozs. Juniplex Alcohol 6% Each ounce contains: * * * Cyanocobalamin (Vitamin B_{12} U.S.P. XIV) 30 mcg." and (ctn.) "List No. 13A 10 cc size (10.50 cc.) Multiple Dose Package Liver Injection U.S.P. Each cc. contains Vitamin B_{12} activity equivalent to 10 mcgms. of Cyanocobalamin."

RESULTS OF INVESTIGATION: Analyses showed that the *liver injection* contained approximately 40 percent and the *Juniplex* contained approximately 70 percent of the declared amounts of vitamin B_{12}.

LIBELED: 5–4–60, N. Dist. Calif.

CHARGE: *Juniplex.* 501(c)—while held for sale, the strength of "*Juniplex*" differed from that which it purported and was represented to possess; 502(a)—the label statement "Each ounce contains: * * * Cyanocobalamin (Vitamin B_{12} U.S.P. XIV) 30 mcg." was false and misleading as applied to the article which contained less than the declared amount of vitamin B_{12}; and 502(a)—the labeling contained statements which represented that the article was of value as a hematinic whenever there was a reason to suspect a deficiency of the vitamin B complex, and in retarded growth of children, which statements were false and misleading in that they represented and suggested that there might be need for supplementing the diet of children with vitamin B complex, which representations were contrary to fact.

Liver injection. 501(b)—while held for sale, the strength of the article differed from the standard for such article as set forth in the United States Pharmacopeia; and 502(a)—the label statement "Each cc. contains vitamin B_{12} activity equivalent to 10 mcgms. of Cyanocobalamin" was false and misleading as applied to the article which contained less than the declared amount of vitamin B_{12}.

DISPOSITION: On 7–7–60, the Chicago Pharmacal Co., Chicago, Ill., claimant, filed an answer denying the allegations of adulteration and misbranding in the libel. On 3–17–61, the claimant having consented to the entry of a decree with the understanding that it should not be deemed to have admitted such allegations in the libel, and the court having found that the articles were adulterated as alleged in the libel, judgment was entered providing for condemnation and destruction of the article.

6566. Rubber prophylactics. (F.D.C. No. 45377. S. No. 25–006 R.)

QUANTITY: 8 ctns., each containing 12 pkgs. of 1-doz. units each, at Tulsa, Okla.

SHIPPED: 11–22–60, from North Kansas City, Mo., by Dean Rubber Mfg. Co.

LABEL IN PART: (Pkg.) "Peacocks Redi-Wet Rubbers in Foil * * * Dean Rubber Mfg. Co. North Kansas City, Mo. * * * An Aid in Preventing Venereal Diseases. No. 12."

RESULTS OF INVESTIGATION: Examination of 150 prophylactics showed that 3 units contained holes and one unit could not be unrolled without tearing.

LIBELED: 12–29–60, N. Dist. Okla.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "An aid in Preventing Venereal Diseases" was false and misleading as applied to an article containing holes and which could not be unrolled without tearing.

DISPOSITION: 1–30–61. Consent—destruction.

6567. Rubber prophylactics. (F.D.C. No. 45175. S. No. 26–687 R.)

QUANTITY: 55 gross ctns. of 3-unit pkgs. each, at Las Vegas, Nev.

SHIPPED: 10–28–60, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Viking Prophylactics * * * Contents ¼ Dozen Sold For the Prevention of Disease Only Dist. by M & M Rubber Co., Kansas City, Mo."

RESULTS OF INVESTIGATION: Examination showed that 3 out of 144 prophylactics examined were defective in that they contained holes.

LIBELED: 12–9–60, Dist. Nev.; amended 12–29–60.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "For the Prevention of Disease" was false and misleading as applied to an article containing holes.

DISPOSITION: 1–24–61. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

6568. Tri-Wonda Treatment (Tri-Wonda Nos. 1, 2, and 3). (F.D.C. No. 34908. S. Nos. 47–121/3 L.)

QUANTITY: 11 100-lb. drums of "Tri-Wonda No. 2" (bulk); 1,526 4-oz. cans of "Tri-Wonda No. 2"; 2,077 2-oz. btls. of "Tri-Wonda No. 1"; and 5,229 2-oz. btls. of "Tri-Wonda No. 3," at Jackson, Miss., in possession of Wonda Products Co.

SHIPPED: The 100-lb. drums of "Tri-Wonda No. 2," between 10–3–52 and 1–13–53, from New York, N.Y.; the bottles of "Tri-Wonda No. 1," on 2–9–53, from Atlanta, Ga.; and the bottles of "Tri-Wonda No. 3," on 2–9–53 and 2–20–53, from Atlanta, Ga.

LABEL IN PART: (Drum) "Special Powdered Tri-Wonda Formula No. 2 * * * Cream of Tartar T V Senna Precipitated Sulphur, XXXX Sugar Phenolphthalein Corn Starch Caution For Manufacturing Processing or Repackaging"; (can) "Contents 4 Ozs. Tri-Wonda No. 2 Laxative Powder Active Ingredients: Cream of Tartar, Senna, Sulphur and Phenolphthalein. * * * Wonda Products Co. Sole Distributors 2805 Arbor Hills Drive, Jackson, Miss."; (btl.) "2 fluid ounces Tri-Wonda No. 1 Suggested for Muscular Aches, Pains, Soreness, Stiffness, and Swellings, Active Ingredients: Nitric Acid and Hydrochloric Acid. Also traces of Salicylic, Tartaric, Acetic and Ascorbic Acids. No Alcohol No Opiate * * * Wonda Products Co. 2805 Arbor Hills Drive, Jackson, Miss."; and (btl.) "2 fluid ounces Tri-Wonda No. 3 Helpful in case of Simple Neuralgia Active Ingredients: Fluid Extract of Jamaica Dogwood, Syrup of Wild Cherry, and Thiamine Hydrochloride 44% Alcohol Not an Opiate * * * Mfg. by Wonda Products Co. 2805 Arbor Hills Drive, Jackson, Miss."

ACCOMPANYING LABELING: Leaflet entitled "Special Bulletin" and printed letters headed "Dear Friend."

RESULTS OF INVESTIGATION: One bottle of "Tri-Wonda No. 1," 2 cans of "Tri-Wonda No. 2," and 3 bottles of "Tri-Wonda No. 3" were assembled by Wonda Products Co. into one carton for shipment to customers. This assortment was called one "*Tri-Wonda Treatment.*" The cans of "Tri-Wonda No. 2" had been packed by Wonda Products Co. from the contents of 100-lb. drums.

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*See also Nos. 6541, 6546, 6547, 6551, 6552, 6554–6559, 6563–6567.

LIBELED: 3–23–53, S. Dist. Miss.

CHARGE: 502(a)—while held for sale, the accompanying labeling of the article designated as the "*Tri-Wonda Treatment*," consisting of one bottle of "Tri-Wonda No. 1," two cans of "Tri-Wonda No. 2," and three bottles of "Tri-Wonda No. 3," and of the bulk material in drums labeled in part "Tri-Wonda Formula No. 2," contained false and misleading representations that the article was an adequate and effective treatment for bursitis, arthritis and rheumatism.

DISPOSITION: On 3–27–53, Mrs. Lela S. Wier, t/a Wonda Products Co., filed an answer to the libel, claiming the articles and denying that they were misbranded. On 2–4–54, the claimant filed an amended answer and counterclaim. The amended answer denied that the articles were misbranded and claimed that the articles had the capacity to give relief from certain symptoms and distress accompanying arthritis and rheumatism. The counterclaim sought an adjudication that the "*Tri-Wonda Treatment*" was effective; that the proceeding was instituted without reasonable cause; that the libel be dismissed; that the property seized be restored; and that claimant have a judgment for costs. On 2–11–54, the claimant filed a motion for the discovery of Government documents containing scientific or technical information relating to the products seized and the issues involved.

On 3–3–54, the Government filed a complaint against Mrs. Lela S. Wier, t/a Wonda Products Co., seeking to enjoin her from introducing into interstate commerce the article of drug "Tri-Wonda" upon the grounds that it was misbranded (see notice of judgment No. 6551 in this supplement). On 3–5–54, the Government filed a motion to take a sample of the seized articles; motion sustained 3–8–54. On 4–9–54, the first set of Government interrogatories was filed, and on 4–16–54, the claimant moved for additional time within which to file objections or answers to the interrogatories; claimant's motion granted 4–19–54. On 5–10–54, the claimant filed some answers and objections to the Government interrogatories; 26 of 30 questions were objected to, 3 were answered directly, and a general, partial, nonspecific answer was made to some of the interrogatories. On 5–24–54, the Government filed a motion for an order to compel further and more complete answers from the claimant. On 7–23–54, the first set of claimant interrogatories was filed. On 7–27–54, the Government filed a subpoena served on Lela Wier which directed her to produce documents. On 7–28–54, the Government filed objections to answering any and all of the claimant interrogatories.

On 8–5–54, the court ordered:

1. The consolidation of the libel and injunction actions for trial; 2. The striking of the claimant's counter claim; 3. The production of the Government documents demanded by the claimant for inspection and copying by the claimant; 4. The answering by the claimant of Government interrogatories Nos. 1 to 30, inclusive, except No. 6 (the formula required by interrogatory No. 5 was ordered answered in secret and kept as a secret by the Government); 5. The answering by the Government of the claimant's interrogatories Nos. 1 to 16, inclusive, except as to Nos. 4, 5, 8, 9 and 10; and 6. The filing of complete answers to the required interrogatories by both the United States and Mrs. Wier on or before 8–17–54. The court also ordered that the claimant, Mrs. Wier, was not required to comply with part of the subpoena duces tecum, namely, that relating to the production of letters from dissatisfied customers.

Thereafter, both sides filed further written interrogatories and the Gov-

ernment filed two series of requests for admissions. Trial on the issues of both the libel and the injunction began on 9–26–55. There were recesses, and the testimony was completed on 6–21–56, after nearly 7 weeks of actual trial. The case was taken under advisement by the court. On 5–29–57, the court handed down its findings of fact and conclusions of law to the effect that the articles were misbranded in that their accompanying labeling contained the false and misleading statement: "Tri-Wonda No. 1 is a powerful medicine—must be in order to relieve one's system of any form of rheumatism." On the same day the court signed a decree providing for the condemnation and destruction of the articles.

6569. Various vitamin products. (F.D.C. No. 44889. S. Nos. 32–392 R, 32–398/9 R, 35–363/4 R, 35–368/71 R, 35–373/4 R, 35–376 R, 35–378 R.)

QUANTITY: 64 100-capsule btls. of *Formula No. 385;* 20 100-capsule btls. of *Formula No. 505;* 24 100-capsule btls. of *Formula No. 616;* 65 100-tablet btls. of *Formula No. 737;* 50 100-tablet btls. of *Formula No. 739;* 42 100-tablet btls. of *Formula No. 748;* 93 100-tablet btls. of *Formula No. 749;* 18 100-capsule btls. of *Formula No. 751;* 10 100-capsule btls. of *Formula No. 752;* 23 100-capsule btls. of *Formula No. 755;* 8 4-oz. btls. of *Formula No. 760;* 5 100-tablet btls. of *Formula No. 785;* and 1 100-capsule btl. of *Formula No. 787,* at New York, N.Y., in possession of George Nemiroff & Co., Inc.

SHIPPED: On various dates during 1959 and 1960, from Baltimore, Md., and Roselle, N.J.

LABEL IN PART: "Formula No. 385 * * * Nemco-Vite Multi-Vitamins"; "Formula No. 505 * * * Nem-B-Globin with Vitamin B–12"; "Formula No. 616 * * * Multigels * * * High Potency Multiple Vitamin Therapeutic Formula"; "Formula No. 737 * * * Thiamin Chloride (Vitamin B–1) 100 mg."; "Formula No. 739 * * * Riboflavin (Vitamin B–2) 10 mg."; "Formula No. 748 * * * Niacin 100 mg."; "Formula No. 749 * * * Niacinamide 50 mg."; "Formula No. 751 * * * Vitamin A (Natural) 25,000 U.S.P. Units"; "Formula No. 752 * * * Vitamin A (Natural) 50,000 U.S.P. Units"; "Formula No. 755 * * * Wheat Germ Oil 3 minims"; "Formula No. 760 * * * Nemco-Bild An Appetite Stimulant with Lysine"; "Formula No. 785 * * * Nemco-Hist Antihistaminic Analgesic-Antipyretic with Vitamin C and Citrus Bioflavonoids"; and "Formula No. 787 * * * Therapeutic M Therapeutic Multi-Vitamins and Minerals with 10 mcg. Vitamin B–12."

ACCOMPANYING LABELING: Booklet entitled "Save On All Drugs & Vitamins at Nemiroff"; leaflets entitled "Vitascorbic No. 26," "Nemco-Vite No. 30," and "Lest You Forget."

RESULTS OF INVESTIGATION: The articles were packed in retail-size containers by the manufacturers and labeled with labels supplied by the dealer.

LIBELED: 9–19–60, S. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling of the articles contained the following false and misleading representations:

(a) That all of the articles, by supplying supplemental quantities of vitamins and minerals to the diet would guard the diet; promote well being; preserve the health of the tissues; provide added endurance, vigor, and growth; assure normal functioning of the digestive tract, nervous system, and other organs and systems of the body;

(b) That the articles listed in the labeling as providing supplemental amounts of vitamin A to the diet would prevent night blindness; help main-

tain resistance; promote cell growth; and assure normal reproductive function;

(c) That the articles listed in the labeling as providing supplemental amounts of vitamin B_1 to the diet would aid in the digestion of starches and sugars; the health and motility of the intestinal tract; vitally support the liver; promote proper function of the nervous system; and aid in various forms of neuritis;

(d) That the articles listed in the labeling as providing supplemental amounts of vitamin B_2 to the diet would guard against sore mouth and tongue, and granular eyelids;

(e) That the articles listed in the labeling as providing vitamin B_6 to the diet would support the digestion of fats and proteins; and aid in certain skin and nervous disorders;

(f) That the articles listed in the labeling as providing supplemental amounts of vitamin B_{12} to the diet would aid in maturing of blood cells; the metabolism of nerve tissues; and promote the growth of the underdeveloped child;

(g) That the articles listed in the labeling as providing supplemental amounts of vitamin C to the diet would guard against gum diseases; aid in the function of certain glands; help in building and strengthening the cement-like substances in the blood vessels; be of value in treatment of physiological and psychological stress; inflammatory conditions; virus and infectious diseases; allergies; heal wounds and severe burns; and prevent simple colds;

(h) That the articles listed in the labeling as providing supplemental quantities of vitamin E to the diet would be of benefit by helping cell metabolism and fertility; and in the treatment and prevention of coronary artery disease, threatened abortion, muscular atrophy, and many other diseases;

(i) That the articles listed in the labeling as providing supplemental amounts of vitamin K to the diet would be essential for the formation of blood clotting substances originating in the liver; and for correction of an increased tendency to bleed;

(j) That the articles listed in the labeling as providing supplemental amounts of folic acid to the diet would improve the utilization of proteins and amino acids;

(k) That the articles listed in the labeling as providing supplemental amounts of niacinamide to the diet would guard against skin disorders; and promote utilization of some of the protein factors; which statements were false and misleading, since the diseases, symptoms, and conditions, stated, suggested, and implied, and the abnormality or impairment of the bodily structures or functions mentioned, are rarely if ever caused by a dietary deficiency of the vitamins mentioned, and since use of the articles would not prevent or correct such diseases, symptoms, or conditions, or correct the impairment of the bodily functions mentioned;

(l) That practically everyone in this country is suffering from, or is in danger of suffering from, a serious dietary deficiency of vitamins and minerals which is likely to result in specific deficiency diseases including rickets, pellagra, scurvy, and goiter, as well as a great number of nonspecific symptoms and conditions; that such dietary deficiency is due to loss in the nutritive value of foods caused by the growing of foods on depleted soils, and by the storage, processing, refining, shipping, and cooking of foods; that there are increased needs for nutrients by the ordinary individual due to physical and psychological stress, to increased intakes of starches and sugars, and to the limitation of

diet below adequate levels by reason of a sedentary mode of life; and that it is considered by health authorities to be advisable and even essential to supplement the diet with vitamins and minerals in order to prevent deficiencies of vitamins and minerals;

Formula No. 785 Nemco Hist, 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the ingredient "Citrus Bioflavonoids," was an active ingredient of the article; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 502(f)(2)—the labeling of the article failed to bear adequate warnings against use, in that said article was for oral use and contained antihistaminic and salicylate ingredients, and its labeling failed to warn that the article should be kept out of the reach of children; that the article might cause drowsiness; that one should not drive or operate machinery while taking the article; and that the article should not be given to children under 6 years of age or the recommended dosage exceeded unless directed by a physician.

Formula No. 385 Nemco-Vite Multi-Vitamins, 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article would be adequate and effective in the prevention and treatment of anemia and liver damage; that the article was essential to blood formation, better nutrition, and better health; that it would prolong life and cause one to live a useful, zestful, and comfortable life; and that it was adequate and effective for skin conditions because of the presence therein of vitamin F.

Formula No. 505 Nem-B-Globin, 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for all types of anemia, including pernicious anemia; headaches; listlessness; poor appetite; shortness of breath; frequent bleeding; and a general "washout" feeling; and would promote better absorption and utilization of protein; aid in maturation of blood cells and metabolism of nerve tissue; and promote growth in the underdeveloped child; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, for the treatment of pernicious anemia.

Formula No. 760 Nemco-Bild, 502(a)—while held for sale, the name "Nemco-Bild" was misleading, since it implied and suggested that the article was a body builder, whereas, the article is not effective for such purpose; and the labeling contained false and misleading representations that the article was effective as an appetite booster, appetite stimulant, and body builder; for retarded growth; for improved protein utilization; and as an aid in converting vegetable protein to the equivalent of the energy-building meat protein.

The libel alleged also that Formula Nos. 748, 749 and 760 were misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods, No. 27400.

DISPOSITION: 10–13–60. Consent—claimed by George Nemiroff & Co., Inc., and relabeled.

6570. Wey-Rite. (F.D.C. No. 45078. S. No. 3–457 R.)

QUANTITY: 13 cases, each containing 12 1-lb. 2-oz. cans and 9 cases, each containing 4 5-lb. cans, at Arlington, Va., in possession of Wey-Rite Potomac Sales Co.

SHIPPED: 9–28–60, from Chicago, Ill., by Life Products International, Inc.

LABEL IN PART: (Can) "Wey-Rite Contains No Drugs or Other Harmful Ingredients * * * Nutritional Health-Weight Control A Delicious Energy Sus-

taining High Protein Food Alternate! Net Weight * * * Manufactured exclusively for Life Research Corporation, 430 N. Michigan Avenue, Chicago 11, Illinois R 1954."

ACCOMPANYING LABELING: Circulars enclosed in each case of the article entitled "Sip a Quickie Meal"; circulars entitled "Nutritional Health Protection" which were printed locally at the request of the dealer; and circulars entitled "You'll enjoy Wey-Rite * * * Hints and Tips" and "Nutritional Food for Health and Weight Control" which were obtained from Life Products International, Inc., Chicago, Ill.

LIBELED: On or about 11–2–60, E. Dist. Va.

CHARGE: 502(a)—when shipped and while held for sale, the can label and the accompanying labeling contained false and misleading representations that the article was adequate and effective for adults, children, and infants, to reduce, control and maintain proper weight and to gain weight safely, while supplying all nutritional needs; while safeguarding and bettering health; while sustaining strength and vital energy; and while satisfying hunger and the desire to eat; to provide quick energy and strength; lengthen life; build up the body; maintain every vital function of the body; look, feel, and do better; for pep and vitality; to be happier; and for a new zest for living, and that the article was adequate and effective to eliminate cholesterol from the blood.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 2–14–61. Consent—claimed by Life Products International, Inc., and brought into compliance with the law by reprocessing, repacking, and relabeling.

6571. Gen-Gen Oyster Liver Extract. (F.D.C. No. 45100. S. No. 25–435 R.)

QUANTITY: 9 cases, each containing 10 individually cartoned btls., at Los Angeles, Calif.

SHIPPED: 9–14–60, from Honolulu, Hawaii, by Pacific Pharmaceuticals, Inc.

LABEL IN PART: (Ctn.) "30 Day Supply Gen-Gen Oyster Liver Extract * * * 60 Tablets of A High Potency Food Supplement Prepared in Japan * * * Imported and Distributed in U.S.A. By Pacific Pharmaceuticals, Inc., Honolulu, Hawaii * * * Gen-Gen is not a drug but a high potency food supplement. Extracts from 20 to 27 oyster livers are required for each tablet. * * * Ingredients (One Tablet) Milligrams Special Oyster Liver Extract 187.5 Vitamin B_1 (5 times minimum daily requirement) 5.0 Taurine 25.0 Carrot Extract (Radix Panacis) 32.5 * * * The need for Radix Panacis extract and taurine in human nutrition has not been established."

LIBELED: 11–22–60, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the name of the article "*Gen-Gen Oyster Liver Extract*" was false and misleading in that it suggested and implied, since liver extracts are commonly employed in the treatment of pernicious anemia, that the article was adequate and effective for the treatment of pernicious anemia, whereas, the article was not adequate and effective for such purposes; and the label of the article bore statements which represented and suggested that the article was adequate and effective to cause the user to feel more alive, which statements were false and misleading since the article was not adequate and effective for such purpose.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 2–6–61. Consent—claimed by Pacific Pharmaceuticals, Inc., and released under bond to be brought into compliance with the law.

6572. Felsol powders and tablets. (F.D.C. No. 45280. S. Nos. 21–721/2 R.)

QUANTITY: 50,070 grams of powders in boxes, and 50,030 grams of tablets in boxes, at Lorain, Ohio, in possession of American Felsol Co.

SHIPPED: The raw materials used in the manufacture of the powders and tablets had been shipped to Lorain, Ohio as follows: iodopyrine, citric acid, and caffeine, from St. Louis, Mo., between 6–3–58 and 1–11–60; and the antipyrine, from Frankfurt, Germany, on 12–2–58.

LABEL IN PART: (Box) "15 Powders Small Size Felsol Each powder (or two tablets) contains: antipyrine, 870 mg. citrated caffeine, 100 mg. iodopyrine, 30 mg." and "30 Tablets Small Size Felsol Each powder (or two tablets) contains: antipyrine, 870 mg. citrated caffeine, 100 mg. iodopyrine, 30 mg."

ACCOMPANYING LABELING: Leaflets in boxes reading in part "Felsol *Powders *Tablets * * * General Measures in Symptomatic Treatment."

CHARGE: 502(a)—while held for sale, the labeling of the articles contained false and misleading representations that the articles were adequate and effective treatments for bronchopulmonary conditions; upper respiratory conditions, colds; influenza; asthma; hay fever; bronchitis; croup; whooping cough; sinusitis; and other conditions.

DISPOSITION: 1–30–61. Consent—claimed by American Felsol Co. and relabeled.

6573. Ocean water. (F.D.C. No. 45342. S. No. 47–468 R.)

QUANTITY: 99 1-gal. btls. at Defiance, Ohio, in possession of Kenneth F. Wilson.

SHIPPED: In July 1960, by Kenneth F. Wilson, from Belmar, N.J.

ACCOMPANYING LABELING: Leaflets reading in part "Worry Clinic, By George W. Crane, M.D., Ph. D.," "Oh, Dr. Crane," and "Chemical Smorgasbord vs. Cancer."

LIBELED: 1–10–61, N. Dist. Ohio.

CHARGE: 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective in the treatment of arthritis, cancer, diabetes, multiple sclerosis, myasthenia gravis, Parkinson's disease, and leukemia; that the product was adequate and effective in providing for rejuvenation, in acting as a "Fountain of Youth"; that it was capable of perking one up physically and mentally; would keep various organs and glands up to par, and would give ones glands and bodily organs a "chemical smorgasbord"; and that the product contained ingredients beneficial to health but not found in the ordinary diet.

DISPOSITION: 2–8–61. Default—destruction.

6574. Serpasil tablets (counterfeit). (F.D.C. No. 44813. S. No. 23–590 R.)

QUANTITY: 1 btl. containing about 3,000 tablets at Kansas City, Kans.

SHIPPED: During 1960, prior to 5–1–60, from Chicago, Ill., by Charles C. Moore.

LABEL IN PART: (Btl.) "Serpasil Tablets 0.25 mg."

RESULTS OF INVESTIGATION: Examination showed that the article was a counterfeit of Serpasil 0.25 milligram tablets.

LIBELED: 10–12–60, Dist. Kans.

CHARGE: 502(a)—while held for sale, the label statement "Serpasil Tablets" was false and misleading since the article was not Serpasil tablets; and 502 (i) (2)—when shipped and while held for sale, the article was an imitation of another drug, namely, Serpasil.

DISPOSITION: 2–2–61. Default—delivered to the Food and Drug Administration.

6575. Thin-Down tablets. (F.D.C. No. 44412. S. No. 67–295 P.)

QUANTITY: 12 cases, each containing 108 individually cartoned 90-tablet btls., at Rivera, Calif.

SHIPPED: 1–7–60, from Edison, N.J., by Revlon, Inc.

LABEL IN PART: (Ctn.) "90 Tablets For Weight Reduction and Figure Control Thin-Down Revlon Appetite Depressant and diet supplement Thin-Down Tablets are formulated to depress the appetite, while supplementing any low-calorie plan of weight reduction with vital minerals and the minimum daily adult requirements of essential vitamins. Directions * * * See enclosed booklet * * * Revlon Pharmacal Division Revlon, Inc., N.Y. Distr. Three Thin-Down Tablets contain 75 mgs. of Phenylpropanolamine Hydrochloride together with * * *."

ACCOMPANYING LABELING: Booklet in carton entitled "Revlon Thin-Down Formula for Beauty."

LIBELED: 4–4–60, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the name "Thin-Down" and statements in the labeling of the article represented and suggested that the article was adequate and effective for weight reduction, figure control, and as an appetite depressant, that it would increase vitality and energy, and that it would help one to have a clearer skin and more lustrous hair, which statements were false and misleading since the article was not adequate and effective for such purposes.

DISPOSITION: 2–2–61. Revlon, Inc., having filed a claim and answer to the libel and later withdrawn such claim and answer, judgment of condemnation was entered and the court ordered that the product be destroyed.

6576. Alfacon tablets, A–C tablets, and Verdogen capsules. (F.D.C. No. 45074. S. Nos. 25–735/7 R.)

QUANTITY: 372 100-tablet btls., 185 200-tablet btls., and 56 500-tablet btls., of *Alfacon tablets;* 273 100-tablet btls. and 66 200-tablet btls. of *A–C tablets;* and 134 30-capsule btls. and 45 90-capsule btls. of *Verdogen capsules*, at Los Angeles, Calif.

SHIPPED: Between 4-21–60 and 9–22–60, from North Kansas City, Mo., by Dayco Laboratories, Inc.

LABEL IN PART: (Btl.) "400 Mg. In Each Tablet ALFACON Natural Organic Concentrated Fresh Alfalfa Juice Coated With Natural Chlorophyll for Locked-In Freshness Distributed by Dayco Products Division of Dayco Laboratories, Inc., North Kansas City, Missouri Alfacon tablets are made from the water-soluble extract of organically grown alfalfa which is harvested when the plants are young, green and succulent. The extract is prepared and dried by a special process designed to preserve the water-soluble nutrients of the fresh green vegetation. Three tablets daily will provide a

daily intake of water-soluble alfalfa nutrients equivalent to about one ounce of fresh alfalfa leaves."; "500 Mg. In Each tablet A–C High Potency Natural Vitamins A and C All In One Tablet Distributed by Dayco Products, Division of Dayco Laboratories, Inc., North Kansas City, Missouri * * * Each Tablet contains: MDR 10,000 IU Vitamin A (Natural Carotene) 250% 75 mg. Vitamin C 250% (Concentrated Rose Hips) Glazed with Natural Vegetable Protein to safeguard potency."; "550 Mg. In Each Capsule VERDOGEN Natural Chlorophyllins Vitamins B_1 and B_6 Distributed by Dayco Products Division of Dayco Laboratories, Inc., North Kansas City, Missouri Each Verdogen Capsule contains: MDR Vitamin B_1 43 mg. 4300% Vitamin B_6 16 mg. * Oxochlor * * 60 mg. *."

ACCOMPANYING LABELING: (*Alfacon tablets*) folders entitled "When Arthritis & Rheumatism Strike," sheets reading in part "Full Analysis," window display sheets reading in part "Alfacon," and advertisement mats reading in part "Rheumatic and Arthritic like pains"; (*A–C tablets*) folders entitled "New Natural A–C Vitamin A and Vitamin C All In One Tablet," display cards entitled "New Natural A–C," and window display sheets entitled "New Natural A–C"; and (*Verdogen capsules*) folders entitled "Pharmaceutical Grade Chlorophyllins," sheets reading in part "Verdogen Capsules * * * A typical Analysis," display cards, and window display sheets reading in part "Verdogen Natural Chlorophllins."

LIBELED: 11–4–60, S. Dist. Calif.

CHARGE: *Alfacon tablets*, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for arthritis, rheumatism, bursitis, and related conditions.

A–C tablets, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an all-purpose vitamin ("All In One Tablet") tablet; and that it was an adequate and effective treatment for dermatitis (acne), chronic infections, rectal lithiasis, burns, skin ulcers, respiratory infection, promotion of growth, prevention of night blindness, building strong bones, colds, essential in infant feeding, sore, swollen, and bleeding gums, and scurvy.

Verdogen capsules, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for difficult breathing caused by respiratory ailments, asthma, anemia, high altitude, dizziness, headache, nausea, anorexia, and chronic heart weakness, wound healing, growth supplementation, burns, and others.

DISPOSITION: 12–21–60. Consent—claimed by Dayco Laboratories, Inc., and released under bond to be brought into compliance with the law.

6577. Lectrofilter Air Cleaner. (F.D.C. No. 44743. S. No. 21–421 R.)

QUANTITY: 46 devices at Cleveland, Ohio.

SHIPPED: During July and September 1959, from Albion, Mich., by Coolerator Div., McGraw-Edison Co.

LABEL IN PART: (Ctn.) "Lectrofilter Portable Air Cleaner."

ACCOMPANYING LABELING: Printed material consisting of "Owners Guide Lectrofilter Air Cleaner Model 101," "Lectrofilter–What is it?," "Presentation of Lectrofilter," "Coolerator Air Filter," "Lectrofilter Gives hay fever and asthma relief . . .," "The World's First Low-Cost Portable * * * Lectro-

filter," "Why Breathe A Teaspoon of Dirt Every Day?," "Now, Relief From Hayfever, Asthma, and other allergies . . .," "Now . . . wonderful relief from . . . Hayfever, Asthma and Dust Allergies," and "Lectrofilter Amazine New Portable Lectrofilter . . ."

RESULTS OF INVESTIGATION: The article consisted of a portable cabinet, housing an electrostatic fiberglass filter, ultra-violet lamp, and electrically operated fan which circulated air through the device.

LIBELED: 7–27–60, N. Dist. Ohio.

CHARGE: 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for relieving allergy conditions, sinus, hay fever and asthma, and for destroying airborne bacteria and viruses.

DISPOSITION: 3–7–61. McGraw-Edison Co., claimant, having represented to the court that it was no longer using the printed material designated in the libel, but was using material approved by the Food and Drug Administration, and having consented to the entry of a decree without admitting the alleged misbranding, judgment of condemnation was entered and the court ordered that all printed material seized with the article be destroyed, and that the article be released under bond for relabeling.

6578. Cool-Mist Humidifier. (F.D.C. No. 45503. S. No. 37–826 R.)

QUANTITY: 10 devices at Philadelphia, Pa.

SHIPPED: 11–2–60, from Milwaukee, Wis.

LABEL IN PART: (Ctn.) "Cool-Mist * * * Portable Room Humidifier."

ACCOMPANYING LABELING: Folders entitled "Humidity Health & Comfort" and a display poster reading in part "Cold-Mist Portable Room Humidifier."

RESULTS OF INVESTIGATION: The article was an electrically operated device which would atomize water and blow the atomized water into the atmosphere by means of an air jet.

LIBELED: 3–6–61, E. Dist. Pa.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was adequate and effective in preventing respiratory infection, the presence and multiplication of disease-causing germs and bacteria in the nasal passages, pneumonia, coughs, colds, and similar ills, dry, scratchy throat, bleary eyes, winter itch, weariness, withdrawal of the body's moisture, and that the article when used as directed would provide for faster respiratory relief, relief from coughs and colds, and continued health.

DISPOSITION: 3–23–61. Consent—claimed by John Oster Mfg. Co., Milwaukee, Wis., and relabeled.

6579. Filtronair Air Purifier device. (F.D.C. No. 45325. S. No. 40–820 R.)

QUANTITY: 11 devices at St. Louis, Mo.

SHIPPED: Between 5–20–60 and 6–16–60, from Glendale, Calif., by Filtronair, Div. of Genge Industries, Inc.

ACCOMPANYING LABELING: Booklets entitled "Is Breathing Killing You," "Electrostatic Precipitation for Your Air Cleaning System," and "Electrostatic Precipitation for Better Health For Better Living"; folders entitled "Filtered Electron Air For Better Living For Better Health"; and data sheets signed "A. J. Salle."

RESULTS OF INVESTIGATION: The device was a portable cabinet containing a honeycomb-shaped electrical precipitator, a mechanical filter, and a fan for continuous recirculating of room air through the filters.

LIBELED: 12–30–60, E. Dist. Mo.

CHARGE: 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for relieving or overcoming heart trouble, asthma, hay fever, allergies, colds, flu, virus conditions, bronchial coughs and ailments, respiratory ailments, sinusitis, shortness of breath, and many serious illnesses; that it guarded health by removing eye and respiratory irritants, bacteria, allergens, and viruses, and that it was essential for general good health.

DISPOSITION: 1–30–61. Default—destruction.

6580. Clear-Air Electronic Air Purifier device. (F.D.C. No. 45081. S. No. 36–165 R.)

QUANTITY: 9 cartoned devices at Bloomfield, N.J., in possession of Variety Electronics Corp.

SHIPPED: 5–18–60, from New York, N.Y., by Radio Merchandise Sales, Inc.

LABEL IN PART: (Ctn.) "Clear-Air Electronic Air-Purifier Deluxe Model CA–64 RMS Bronx 62, N.Y."

ACCOMPANYING LABELING: Instruction sheets entitled "Portable Clear Air Electronic Air-Purifier Model CA–64"; display cards reading in part "Clear Air portable electronic air-purifier"; and circulars reading in part "Portable Electronic Air Purifiers."

RESULTS OF INVESTIGATION: The article was a portable table model type cabinet containing dual fan blades, four ultra-violet lamps, and three nylon filters. In operation the room air was reportedly circulated through the device so as to be exposed to the ultra-violet lamps and then filtered out into the room.

The instruction sheets and display cards described above were received from the shipper, and the circulars were printed at the request of the dealer.

LIBELED: 11–7–60, Dist. N.J.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for aiding sufferers of hay fever, sinus, allergies, and asthma, and for clearing and purifying the air for better health.

DISPOSITION: 1–9–61. Default—delivered to the Food and Drug Administration.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 6541 TO 6580

PRODUCTS

[1] (6546, 6552) Injunction issued.

[1] (6546, 6552) Injunction issued.

[2] (6548, 6554, 6560, 6565, 6568) Seizure contested.

[3] (6547) Seizure contested. Contains orders of the court.

[4] (6551) Injunction issued. Contains findings of fact, conclusions of law and opinion of the court.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (6546, 6552) Injunction issued.
[2] (6548, 6554, 6560, 6565, 6568) Seizure contested.
[5] (6562) Contempt of injunction.
[6] (6550) Prosecution contested.

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[2] (6548, 6554, 6560, 6565, 6568) Seizure contested.
[3] (6547) Seizure contested. Contains orders of the court.
[4] (6551) Injunction issued. Contains findings of fact, conclusions of law, and opinion of the court.
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[6] (6550) Prosecution contested.

U.S. GOVERNMENT PRINTING OFFICE:1962

D.D.N.J., F.D.C. 6581–6620 Issued July 1962

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6581–6620

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent, and (2) an injunction proceeding terminated upon the entry of a permanent injunction after a trial by the court. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the injunction proceedings are against the *firms* and *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *July 25, 1962.*

CONTENTS*

*For omission of, or unsatisfactory, ingredients statements, see Nos. 6584, 6586, 6589; an imitation of another drug, No. 6586; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 6584, 6586; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6584, 6586, 6592.

643889—62——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6581–6620

Adulteration, Section 501(a)(1), the article consisted in part of a filthy substance; Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its quality fell below the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions, or by children, where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6581. Hope's Worm-Rid. (Inj. No. 368.)

COMPLAINT FOR INJUNCTION FILED: 12–28–59, E. Dist. Mo., against the Hope Co., a corporation, Clayton, Mo., Hope J. Anderson, president and treasurer of the Hope Co., and Na-Spra, Inc., Maplewood, Mo.

NATURE OF BUSINESS: The Hope Co. promoted and sold a drug intended for use without a prescription in the treatment of worm infestation in humans. Each 5-cc. teaspoonful of syrup contained piperazine citrate equivalent to 500 mg. piperazine hexahydrate. The Hope Co. and Hope J. Anderson solicited orders for the drug by means of form letters; they prepared and arranged for the printing of all labeling of the drug, and furnished the formula and labels to Na-Spra, Inc. Na-Spra, Inc., manufactured the drug according to the formula supplied by the Hope Co. and Hope J. Anderson, and packaged the drug in 4-oz. bottles to which the labels supplied by the Hope Co. and Hope J. Anderson were affixed. All customer orders for the drug were initially received by the Hope Co. and Hope J. Anderson, and after such receipt instructions were issued by the Hope Co. and Hope J. Anderson pursuant to which shipments of the drug were made to the customers by Na-Spra, Inc., in the name of the Hope Co. Na-Spra, Inc., would inform the Hope Co. and

Hope J. Anderson when the shipments of the drug were made and after receipt of such information the Hope Co. and Hope J. Anderson would bill the customers direct.

CHARGE: The complaint alleged that the article of drug designated by the name of *"Hope's Worm-Rid"* was a new drug within the meaning of 201(p) in that its composition in respect to piperazine hexahydrate was such that the drug was not generally recognized among experts, qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, and suggested in the labeling of the drug, namely, for use without a prescription in the treatment of worm infestation in humans.

The complaint alleged further that when caused to be introduced and delivered for introduction into interstate commerce by the defendants, the drug was in violation of 505(a) in that the drug so labeled was a new drug for which no application filed pursuant to 505(b) was effective.

The complaint alleged further that the defendants violated 301(d) by their acts of causing the introduction and delivery for introduction into interstate commerce of such drug, so labeled, which was in violation of 505(a).

DISPOSITION: On 12–28–59, a temporary restraining order was issued. On 1–18–60, the defendants appeared and filed an answer denying that the article was a new drug. Subsequently, the defendants filed interrogatories and the Government filed answers.

On 1–21–60 and 1–22–60, the Government's motion for a preliminary injunction was heard and, at that time, the parties stipulated that no new drug application had been filed with respect to this drug and that the record of the hearing for a preliminary injunction would become a part of the record of this suit on final hearing.

On 2–22–60, the defendants filed an amended answer containing the previous denials and further alleging that the Federal Food, Drug, and Cosmetic Act was unconstitutional, especially the provisions relating to new drugs and relating to the United States District Court's jurisdiction to restrain violations of the Act.

On 3–31–60, a preliminary injunction was granted. During a hearing held 6–3–60 and 6–6–60, on the motion for a permanent injunction, the Government's motion to quash the defendant's subpoena of two Food and Drug Administration officials was taken under advisement by the court, and, upon the oral motion of the Government, the court ruled that the defendants were to inform the court within 5 days concerning the testimony that the defendants expected to obtain from the subpoenaed officials.

On 8–16–60, the court sustained the Government's motion to quash and rendered the following memorandum opinion:

WEBER, *District Judge:*

MEMORANDUM

"There is presently pending, and unruled upon, the matter of the issuance of subpoenas to Dr. Ralph G. Smith, Director of the New Drug Branch of the Food and Drug Administration, and Dr. William H. Kessenich, Director of the Bureau of Medicine of the Food and Drug Administration, and the Motion filed by plaintiff to quash said subpoenas. After a hearing upon the Motion to Quash, the Court requested of defendant a statement as to evidence and proof expected from the above witnesses, for the reason that they both reside in

Washington, D.C., and are the heads of governmental departments. Defendant has filed said statement of expected proof and the Court has reviewed same and determines as follows:

"1. Defendant states that their testimony would be of probative value and that from a review of prior statements, testimony and published declarations, it is expected they will testify to facts to sustain defendant's answer to plaintiff's Petition. This is testimony which can be introduced by other witnesses and if prior statements, testimony and published declarations were inconsistent, it would amount to an effort by defendant to impeach its own witness or witnesses. The matter of probative value of the testimony is involved in the remaining statements of expected proof under paragraph 5 thereof and will be dealt with in the succeeding paragraphs of this Memorandum.

"2. Sub-paragraphs (a), (b) and (c) of paragraph 5 of defendant's expected proof call for the testimony of these witnesses to show standards, tests and rules for determining whether or not a drug is safe or a new drug. The statutes determine such standards. See Title 21, §§ 321(p) and 355(a). Therefore, such proof is immaterial as the Court will be guided by the statutory definitions.

"3. Sub-paragraphs (d) and (e) of paragraph 5 of defendant's expected proof do not concern the question at issue in this cause. The issue is not whether the drug could be used upon the market for testing and is not its use in order to determine its known effect, but the question is whether or not the drug in question is generally recognized among qualified experts as safe for use under the conditions prescribed, recommended or suggested on the labeling thereof. Therefore, such proof is incompetent and irrelevant.

"4. Sub-paragraphs (f), (h), (m), (r), (u) and (v) of paragraph 5 of defendant's expected proof are matters which can likewise be proven by other witnesses, and in fact, proof thereon has already been offered in this cause and therefore would be no more than cumulative.

"5. Sub-paragraphs (g), (o) and (w) of paragraph 5 of defendant's expected proof call for matters which are the final conclusion to be passed on by this Court and therefore invade the province of the Court and would be incompetent and irrelevant.

"6. Sub-paragraphs (i), (j), (l), (s) and (t) of paragraph 5 of defendant's expected proof are immaterial to the issue as to whether or not the drug is generally recognized among qualified experts and therefore such evidence is incompetent.

"7. Sub-paragraph (k) of paragraph 5 of defendant's expected proof is inconsistent with sub-paragraph (j) and exactly the reverse thereof and therefore immaterial, incompetent and irrelevant.

"8. The Court has conferred with counsel for the government concerning sub-paragraphs (n), (p) and (q) of paragraph 5 and the government will admit that there has been no report to the Food and Drug Administration of any illness or adverse complaint as a result of the use of Hope's Worm-Rid from the date of its first shipment to the time of the granting of the preliminary injunction herein and that there is no such thing as a drug devoid of any toxic effects to some persons. Sub-paragraph (q) is cumulative to (p) aforesaid.

"Therefore, the Motion to Quash will be sustained."

On 5–12–61, the court made the following findings of fact and conclusions of law:

WEBER, *District Judge:*

STATEMENT

"This matter was tried before the Court upon plaintiff's Complaint for Permanent Injunction. The Complaint alleges that the defendants have caused to be introduced and delivered for introduction into interstate commerce a drug known as 'Hope's Worm-Rid,' in violation of 21 U.S.C. 331(d). A permanent injunction against the continuance of these activities is sought under Section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332(a)) on the ground that the drug is a 'new drug' for which no new drug

application has been filed pursuant to Section 505(b) of the Act (21 U.S.C. 355(b)).

"The defendants have admitted by their Answer and by stipulation that they are manufacturing, advertising, and selling Hope's Worm-Rid in interstate commerce; that this drug contains, as its active ingredient, piperazine citrate; and that they have not filed an effective application for this drug under section 505(b) of the Act (21 U.S.C. 355(b)). The sole factual issue in dispute is whether this drug is a 'new drug' within the meaning of 21 U.S.C. (p)(1).

"A temporary restraining order was issued herein and upon motion of the plaintiff and the taking of testimony a preliminary injunction was granted. By stipulation the testimony taken at the hearing for the preliminary injunction is included as part of the record of the trial for the permanent injunction.

"The Court, having heard the evidence submitted by the parties and being now fully informed, adopts the following as its Findings of Fact and Conclusions of Law.

FINDINGS OF FACT

"1. The defendant, the Hope Company, is a corporation organized and existing under the laws of the State of Illinois and doing business at Clayton, Missouri.

"2. The defendant, Hope J. Anderson, an individual, is the president and treasurer of the Hope Company and is primarily responsible for its policies and activities.

"3. The defendant, Na-Spra, Inc., is a corporation organized and existing under the laws of the State of Missouri and doing business at Maplewood, Missouri.

"4. The defendants have been engaged in the business of preparing, selling, and causing to be introduced and delivered for introduction into interstate commerce an article designated by the name 'Hope's Worm-Rid,' which is manufactured in accordance with the following formula:

Piperazine Hexahydrate	—51.6 lbs.
Citric Acid	—30 lbs.
Methyl Paraben	—43.2 grams
Propyl Paraben	—21.6 grams
Sugar	—270 lbs.
Cherry Flavor	—300 cc.
Amaranth Color	—22.8 grams
Water	—to make 60 gallons

The active ingredient of the final product is piperazine citrate.

"5. The article, Hope's Worm-Rid, when caused to be introduced and delivered for introduction into interstate commerce is, by its labeling, offered for sale over-the-counter to lay persons, without the need for a physician's prescription, for use in the cure and treatment of pin and roundworm disease infections in humans.

"6. Hope's Worm-Rid is an article intended for use in the cure and treatment of diseases in man.

"7. The use of piperazine citrate in the quantities prescribed, recommended or suggested in the labeling of Hope's Worm-Rid may cause a variety of toxic side effects including sensitivity reactions such as hives; serum sickness; neurological disturbances such as disturbances of vision, muscular weakness, staggering, dizziness, and in-co-ordination of movement; and nausea, vomiting and diarrhea.

"8. These toxic reactions may require treatment by a physician with drugs which may be dispensed only on a physician's prescription.

"9. Except in rare instances pinworm and roundworm infections cannot be accurately diagnosed except by a physician.

"10. The symptoms of pinworms and roundworms include one or more of a variety of generalized symptoms such as abdominal pain, headaches, fatigue, nail biting, nervousness, irritability, 'not doing well,' loss of weight, and itching in the anal region. There are a wide variety of other diseases which exhibit one or more of these symptoms which are not amenable to treatment with Hope's Worm-Rid. The distribution of Hope's Worm-Rid, without

the requirement of a physician's prescription may therefore result in its use by many persons not suffering from either pinworms or roundworms. These persons would be subjected to the risk of the toxic effects of piperazine citrate without any medical justification.

"11. On the basis of the facts set out in Findings of Fact 4 through 10, the six highly qualified physicians and pharmacologists who testified for the plaintiff stated that they did not recognize the use of piperazine citrate as prescribed, recommended and suggested on the label and labeling for 'Hope's Worm-Rid' as being safe. This conclusion was reached by balancing the expected benefits to health from unrestricted sales against the dangers involved in such a use. They further testified that this is the consensus of medical and pharmacological opinion.

"12. Witnesses for the defendants stated that piperazine citrate has been safely and effectively used in the treatment of pinworms and roundworms under the supervision of physicians and that it is a safe drug. One witness testified that in his opinion its use as prescribed, recommended and suggested in the labeling of Hope's Worm-Rid is safe and generally recognized as safe.

"13. The testimony of the experts in this case establishes the existence of a difference of expert opinion concerning the safety of Hope's Worm-Rid for use under the conditions prescribed, recommended and suggested in its label. It is not, therefore, generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under such conditions.

"14. Defendants have not filed a New Drug Application with the Secretary of Health, Education, and Welfare which has become effective with respect to Hope's Worm-Rid.

"15. The defendants will, unless enjoined, continue to market Hope's Worm-Rid in interstate commerce under its present labeling.

CONCLUSIONS OF LAW

"1. This Court has jurisdiction of the parties and the subject matter of this action under the provisions of 21 U.S.C. 332(a).

"2. The article designated as Hope's Worm-Rid is a 'drug' within the meaning of 21 U.S.C. 321(g).

"3. The existence of a genuine difference of medical opinion among experts, qualified by scientific training and experience to evaluate the safety of a drug, on the question of whether a drug is safe, requires a conclusion that the drug is not generally recognized as safe under such conditions; *The Merritt Corporation* v. *Folsom*, 165 F. Supp. 418 (D.D.C., 1958); *United States* v. *354 Bulk cartons * * * Trim Reducing Aid Cigarettes*, 178 F. Supp. 847 (D.N.J., 1959).

"4. The drug, Hope's Worm-Rid, is a 'new drug' within the meaning of 21 U.S.C. 321(p)(1).

"5. Said 'new drug' when caused to be introduced and delivered for introduction into interstate commerce by the defendants is in violation of 21 U.S.C. 355(a) in that no application filed pursuant to 21 U.S.C. 355(b) is effective.

"6. By causing the introduction and delivery for introduction into interstate commerce of said 'new drug,' without an effective application, the defendants have been violating the provisions of 21 U.S.C. 331(d).

"7. The United States of America is entitled to a permanent injunction restraining the defendants, their officers, agents, servants, employees and representatives and all persons in active concert or participation with them or any of them from introducing or causing to be introduced and delivering and causing to be delivered for introduction into interstate commerce, said drug which is designated as Hope's Worm-Rid, and labeled for use without a prescription in the treatment of worm infestation in humans, or any other drug of similar composition and labeling unless and until an application filed pursuant to 21 U.S.C. 355(b) is effective with respect to such drug under such conditions. An order will be entered granting an injunction as prayed in the Complaint."

On the same day, the court issued a decree of permanent injunction enjoining the defendants from directly or indirectly introducing and causing to be introduced and delivering and causing to be delivered for introduction into

interstate commerce, the drug which was designated as *"Hope's Worm-Rid"* and labeled for use without a prescription in the treatment of worm infestation in humans, or any other drug of similar composition and labeling unless and until an application filed pursuant to 505(b) is effective with respect to such drug.

6582. Dexules timed disintegration capsules and Phenamine tablets. (F.D.C. No. 44896. S. Nos. 21–435/6 R.)

QUANTITY: 97 30-capsule btls. of *Dexules timed disintegration capsules* and 97 90-tablet btls. of *Phenamine tablets*, at Cleveland, Ohio.

SHIPPED: 5–10–60 and 6–1–60, from Syracuse, N.Y., by Approved Pharmaceuticals Corp.

LABEL IN PART: (Btl.) "Timed Disintegration Dexules All Day Appetite Suppressant Approved Pharmaceutical Corp. Syracuse * * * New York Each Capsule Contains: Phenylpropanolamine Hydrochloride 75 mg., Protein Hydrolysate 15 mg. specially prepared to disintegrate over a 8 to 10 hour period for continuous appetite suppression. Dosage * * * Caution * * * 01136" and "30 Day Treatment Phenamine For Appetite Suppression To Aid Weight Reduction Nydegger Pharmacy, 22 Colonial Arcade Dist. Cleveland 14, Ohio Each tablet contains Phenylpropanolamine Hydrochloride 25 mg. Dosage * * * Caution."

LIBELED: 9–20–60, N. Dist. Ohio.

CHARGE: *Dexules timed disintegration capsules*, 502(a)—when shipped, the bottle label of the article contained false and misleading representations that the article was adequate and effective as a treatment for appetite suppression; 502(a)—the statements "Just One Capsule Suppresses Appetite All-Day-Long" and "Just One-A-Day Reduce 5–10–20 Pounds," appearing on the shipping carton label, represented and suggested that the article was adequate and effective as an appetite suppressant, that it would suppress appetite all day long, and that it was adequate and effective to reduce weight, which statements were false and misleading since the article was not adequate and effective for such conditions and purposes; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to 505(b) was not effective with respect to such drug.

Phenamine tablets, 502(a)—when shipped, the bottle label of the article contained false and misleading representations that the article was adequate and effective as a treatment for appetite suppression and weight reduction; and 502(a)—the statements "Reduce," "Eat Less—No Hunger Pangs—Safe Now! Lose Weight Scientifically – A True Appetite Depressant," and "Appetite Depressant Tablets," appearing on the shipping carton label, represented and suggested that the article was adequate and effective as a treatment for appetite suppression and weight reduction, which statements were false and misleading since the article was not adequate and effective as a treatment for such conditions and purposes.

DISPOSITION: Nydegger Pharmacal Co., Cleveland, Ohio, and Approved Pharmaceuticals Corp., Syracuse, N.Y., claimants, filed an answer denying that the articles were misbranded. The Government then served interrogatories upon the claimants. On 6–6–61, the claimants having failed to answer the interrogatories, the court granted the Government's motion for default judgment, and entered a decree of condemnation and destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6583. Vitamin B_{12} tablets and Folibex 12 Capsulettes. (F.D.C. No. 45497. S. Nos. 3–417/8 R.)

QUANTITY: 46 100-tablet btls. of *vitamin B_{12} tablets;* and 3 drums containing a total of approximately 56,840 tablets, 15 250-tablet btls., 41 100-tablet btls., and 78 50-tablet btls. of *Folibex 12 Capsulettes*, at Washington, D.C., in possession of Babbitt Cut Rate Stores, Inc.

SHIPPED: 3–19–60, from Long Island City, N.Y. (*vitamin B_{12} tablets*), and 6–2–60, from Cleveland, Ohio (*Folibex 12 Capsulettes*).

LABEL IN PART: (Btl.) "Vitamin B_{12} Tablets 50 mcg. * * * Distributed by National Vitamin Corporation, Washington, D.C. Indications: As an Appetite Stimulant"; (drum) "Manufactured for: Babbitt Drug Co. Washington, D.C. Contents 24,420 * * * No. 50 Dark Red Code: O.A.D.E. Lot No. 4557 Formula Contains"; and (btl.) "Folibex 12 Each Capsulette Contains: Vitamin B_{12} . . . 10 mcg. (as present in concentrated extractives from streptomyces fermentations). Ferrous Sulfate Exsiccated. . . . 200 mg. Liver Fraction–2. . . . 300 mg. Folic Acid. . . . 0.33 mg. Vitamin C. . . . 75 mg. Distributed by General Vitamin Corp. Washington, D.C. * * * Average Adult Dose 3 Capsulettes Daily as Directed by the Physician."

RESULTS OF INVESTIGATION: The articles were shipped in bulk and repacked and labeled by the dealer.

LIBELED: 2–27–61, Dist. Columbia.

CHARGE: *Vitamin B_{12} tablets*, 502(a)—while held for sale, the label statement "Indication: As an Appetite Stimulant" was false and misleading since it was contrary to fact.

Folibex 12 Capsulettes, 503(b)(4)—while held for sale, the article was subject to 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The libel alleged also that another article was misbranded under the provisions of the Act relating to foods, as reported in notices of judgment on foods.

DISPOSITION: 6–8–61. Consent—claimed by Babbitt Cut Rate Stores, Inc., and released for relabeling.

6584. Amphetamine sulfate tablets. (F.D.C. No. 45472. S. No. 24–125 R.)

QUANTITY: 20,000 tablets at Kansas City, Kans., in the possession of John Richard Sallee.

SHIPPED: 2–16–61, from outside the State of Kansas.

LIBELED: 2–16–61, Dist. Kans.

CHARGE: 502(b)—while held for sale, the article failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; 502(e)(1)—the labels failed to bear the common or usual name of the drug; 502(f)(1)—the labeling failed to bear adequate directions for use and the article was not exempt from that requirement since it was a prescription drug in the possession of a person not lawfully engaged in dispensing prescription drugs; and 503(b)(4)—the article was subject to 503(b)(1) and it failed to bear the label statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 6–13–61. Default—destruction.

6585. Soothene ointment. (F.D.C. No. 45480. S. No. 16–346 R.)

QUANTITY: 11 cases, 144 ctnd. tubes each, at Cincinnati, Ohio.

SHIPPED: 11–23–60, from St. Louis, Mo., by Neal Pharmacal Co. (St. Louis Magnesia Co.).

LABEL IN PART: (Tube and ctn.) "Soothene Contents 1 Oz. A Stainless Ointment * * * Active Ingredients: Carbolic Acid 3%; Zinc Oxide and Menthol in a specially formulated, soothing base. * * * Prepared for Soothene Medicine Co. Cincinnati, Ohio."

LIBELED: 2–16–61, S. Dist. Ohio.

CHARGE: 503(b)(4)—when shipped, the article was a drug subject to 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 3–22–61. Default—destruction.

6586. Reserpine tablets, dextro-amphetamine sulfate tablets, and Dexabarbital tablets. (F.D.C. No. 45324. S. Nos. 45–621/4 R, 45–627 R, 45–631 R.)

QUANTITY: 2 unlabeled jars containing a total of approximately 1,150 tablets of reserpine, purporting to be Serpasil, but being counterfeits thereof with "Ciba" embossed on one side of each tablet and the letter "S" scratched on the jar lids; 1 unlabeled tin containing approximately 2,900 orange-colored heart-shaped single-scored tablets of dextro-amphetamine sulfate, purporting to be Dexedrine Sulfate tablets, but being counterfeits thereof; 4 btls. containing a total of approximately 3,400 orange-colored heart-shaped single-scored tablets labeled in part "Dextro-Amphetamine Sulfate"; and 8 btls. containing a total of approximately 7,900 small green heart-shaped single-scored tablets labeled in part "Dexabarbital," at Aberdeen, N.C., in possession of Craig Drug Co.

SHIPPED: 12–6–60, by William L. "Tex" Palmer, or his son, William Palmer, of Palmer & Co., Houston, Tex.

LIBELED: 1–4–61, M. Dist. N.C.; amended libel 1–20–61.

CHARGE: Tablets purporting to be Serpasil tablets and Dexedrine Sulfate tablets, 502(b)—while held for sale, the tablets failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents; 502(e)(1)—the labels of the tablets failed to bear the common or usual name of the drugs; 502(f)—the labeling of the tablets failed to bear (1) adequate directions for use and (2) adequate warnings against use; 502(i)(2)—the tablets were imitations of other drugs; and 503(b)(4)—the labels of the tablets failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Tablets labeled in part "Dextro-Amphetamine Sulfate." 502(b)(1)—while held for sale, the tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and 502(i)(2)—the tablets were an imitation of another drug.

Tablets labeled in part "Dexabarbital," 502(b)(1)—while held for sale, the tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: 2–15–61. Default—delivered to the Food and Drug Administration.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE*

6587. Bey Proto-X, Bey VA, Bey Natural VC, Ro-Qee-Jel capsules, Bey Vita RG Soya Lecithin, Bey Vita yeast tablets. (F.D.C. No. 44678. S. Nos. 26–082/7 R.)

QUANTITY: 20 btls. of *Bey Proto-X;* 74 btls. of *Bey VA;* 44 btls. of *Bey Natural VC;* 8 btls. of *Ro-Qee-Jel capsules;* 90 btls. of *Bey Vita RG Soya Lecithin;* and 2 cases, each containing 48 90-tablet btls. of *Bey Vita yeast tablets*, at Los Angeles, Calif.

SHIPPED: 5–5–60, from Seattle, Wash., by Hamid Bey.

LABEL IN PART: "Bey Proto-X Amino Acids with Vitamin B-12 and Vitamin B-1 Water Soluble Protein A Dietary Food Supplement – Net Weight 4 Ounces * * * Distributed by Bey Vita Products Co. 2015 Beverly Boulevard – Los Angeles 57, California"; "30 Capsules Bey VA Each capsule contains: 25,000 U.S.P. Units Vitamin A Palmitate as processed from lemon grass oil, with diluents in gelatine capsule * * * Distributed by Bey Vita Products Co. * * * Los Angeles 57, Calif."; "Bey Natural VC Natural Concentrate Extract Rose Hips with Rutin Vitamin C 100 mg. Rutin 2 mg. Net Contents 50 Capsules * * * Distributed by Bey Vita Products Co."; "30 Capsules Ro-Qee-Jel Capsules A Food Supplement * * * Each capsule contains: Royal Queen Bee Jelly 40 mg. Vitamin B-1 (Thiamin) 5 mg. Vitamin B-12 5 micrograms * * * Royal Queen Bee Jelly Co. of Michigan 12751 Capital – Oak Park 37, Michigan"; "100% Pure Lecithin * * * Bey Vita RG Soya Lecithin Net Weight 8 oz. Each tablespoonful (7.5 grams) contains: Choline 250 Mg. Inositol 250 Mg. Phosphorus 225 Mg. Distributed by Bey Vita Products Co."; and "Bey Vita Yeast Natural Complex Yeast Extra Potency – Special Strain Yeast Tablets Natural Rich Source B-Complex, Each tablet contains special grown yeast that is 25 times more potent in B–1 than the official minimum requirements for yeast and 150 times more potent in B-2 than those requirements. Net Contents – 90 Tablets Distributed by Bey Vita Products Co. * * * Los Angeles 57, California."

RESULTS OF INVESTIGATION: The articles were offered orally for diseases and conditions, as set forth below, by and on behalf of Hamid Bey, the promoter of the articles, during a series of classes and lectures at a Seattle, Wash., hotel between 4–18–60 and 5–4–60.

LIBELED: 6–23–60, S. Dist. Calif.

CHARGE: 502(f) (1)—when shipped and while held for sale, the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended, namely, (*Bey Proto-X*) in the treatment of diabetes, stomach ulcers, and arthritis; (*Ro-Qee-Jel capsules*) in the treatment of cataracts, glaucoma, drunkenness, heart trouble, degenerated muscles, and arthritis; (*Bey Vita RG Soya Lecithin*) for inflammation of the lining of the veins, brittle veins, brittle capillaries, brittle blood vessels, impaired circulation, sluggish blood, anemia, abnormal heart and blood pressure, obesity, liver trouble, kidney trouble, and blood trouble; (*Bey VA*) bad eyesight, cataracts, glaucoma, liver ailments, poor blood, and arthritis; (*Bey Natural VC*) infected

*See also Nos. 6584, 6586.

blood, kidney infection, high blood pressure, capillary fragility, impaired circulation, stomach ulcers, varicose veins, anemia, excessive mucous in sinuses, ears, and membranes, and arthritis; and (*Bey Vita yeast tablets*) poor digestion, obesity, duodenal ulcers, intestinal ulcers, impaired nerves and impaired muscles.

The *Bey Proto-X*, *Ro-Qee-Jel capsules*, *Bey Vita RG Soya* and *Lecithin*, were alleged also to be misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 3–27–61. Default—destruction.

6588. Amphetamine tablets and capsules. (F.D.C. No. 45049. S. Nos. 74–641/54 R.)

QUANTITY: Approximately 122,000 tablets and capsules of amphetamine in the possession of Emmett D. Nalley, Washington, Ga.

SHIPPED: On unknown dates, from outside the State of Georgia.

LIBELED: 2–23–61, S. Dist. Ga.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use and the articles were not exempt from such requirement since the articles were in the possession of a person who was not regularly engaged in the manufacture, transportation, storage, or distribution of prescription drugs, and since the articles were not to be dispensed upon prescription.

DISPOSITION: No claimant having appeared, the court, on 4–13–61, entered a decree of condemnation, and upon being advised that the articles may be used as evidence in a criminal proceeding before the court, ordered that the marshal retain the articles in his possession until otherwise directed.

6589. Cough syrup. (F.D.C. No. 44384. S. No. 36–521 R.)

QUANTITY: 2 50-gal. bbls. and 114 cases, each containing 36 3-oz. btls., at Nanticoke, Pa., in possession of Mrs. Chesterine M. Wolfe.

SHIPPED: 1–21–59 and 4–17–59, from Norwich, N.Y.

LABEL IN PART: (Bbl.) "Cough Syrup * * * Alcohol 6% Active Ingredients in each fluid ounce: Chloroform 2 minims White Pine Bark, extractive from 13 grs. White Cherry Bark 30 grs. Squill, extractive from .8 grs. Oil Pine Tar .128 grs. Ammonium Chloride 8.0 grs. Sodium Chloride 12.0 grs. Malt Syrup 6.0 grs. Menthol .08 grs." and (btl.) "Austins Cough Healer With Wild Cherry and Menthol * * * This Product contains–White Pine–Tar–Wild Cherry, Menthol and other drugs * * * T. J. Wolfe, Plymouth, Pa."

RESULTS OF INVESTIGATION: The article in the bottles was repacked from the above-described bulk stock by Thomas J. Wolfe (deceased), Plymouth, Pa.

LIBELED: 3–24–60, M. Dist. Pa.

CHARGE: 502(a)—while held for sale, the labeling of the article (bulk and repacked), namely, the repack bottle label, bore the name "Cough Healer" and contained statements which represented and suggested that the article was an adequate and effective treatment for healing coughs of all types, including long standing and troublesome coughs, hoarseness, colds, bronchitis, bronchial asthma, whooping cough, and croup, which name and statements were false and misleading since the article was not effective for such conditions and purposes; 502(e)(2)—the label of the repacked article failed to

bear the common or usual name of each active ingredient; and 502(f)(2)—the labeling of the repacked article failed to warn that persons with a high fever or persistent cough should not use such article unless directed by a physician.

DISPOSITION: 5–24–61. Consent—claimed by Mrs. Chesterine M. Wolfe, and relabeled.

6590. Headache powders. (F.D.C. No. 45262. S. No. 1–687 R.)

QUANTITY: 2 drums containing a total of 190 lbs. of acetanilid; 3 drums containing a total of 750 lbs. of aspirin; 2 drums containing a total of 170 lbs. of caffeine anhydrous powder; 2 drums containing a total of 800 lbs. of potassium bromide; and 8,640 10¢ pkgs., 2,800 5¢ pkgs., 2,800 samples of the 10¢-size pkgs., and 28,900 samples of the 5¢-size pkgs., of headache powders, at Atlanta, Ga., in possession of B. B. Headache Powder Co..

SHIPPED: Between 12–19–58 and 1–14–60, from New York, N.Y.

LABEL IN PART: (Drum) "NYQ 100-POUNDS ACETANILID N.F. POWDER"; "250-Pounds ACID ACETYLSALICYLIC ASPIRIN U.S.P. 80 Mesh Powder"; "NYQ 100-Pounds CAFFEINE U.S.P. ANHYDROUS POWDER"; and "NYQ 400 pounds POTASSIUM BROMIDE N.F. GRANULAR"; (pkgs.) "4 Doses 10¢ B–B Simple Headaches Simple Neuralgia Each powder contains 2½ grains acetanilid and 7½ grains potassium bromide combined with aspirin and caffeine for the relief of the discomfort of Pain due to Simple Headache and Neuralgia, Head Colds, Minor Muscular Pains, and as a sedative in Simple Nervousness * * * Prepared by B.B. Headache Powder Co. Atlanta, Ga."; "4 Doses 16 Grs. Each * * * B–B Free Sample Not For Sale 10¢ * * * B.B. Headache Powder Co."; "2 doses 5¢ B–B * * * B.B. Headache Powder Co." and "5¢ Quick Relief of Pain and Discomfort * * * Two Powders 16 Grs. Each B–B Free Sample Not for Sale * * * B–B Products Company."

ACCOMPANYING LABELING: 232,000 "5¢" package labels, 318,000 "10¢" package labels, and an unknown number of display cartons reading in part "This carton contains 3 Dozen Packages of 'B–B' Headache Powders 10¢ Sizes B–B Quick Relief For Headaches and Neuralgia * * * Prepared by B–B Products Company Atlanta, Ga. * * * Quick Relief For Minor Muscular Aches and Pains."

RESULTS OF INVESTIGATION: The powders in the 5¢ and 10¢ packages and in the sample packages were manufactured by the B. B. Headache Powder Co. from the above mentioned raw materials.

LIBELED: 12–2–60, N. Dist. Ga.

CHARGE: 502(f)(2)—while held for sale, the labeling of the article failed to bear a warning that the article should be kept out of the reach of children to avoid accidental poisoning, and that overdosage or continued use may result in serious blood disturbances.

DISPOSITION: 5–26–61. Consent—claimed by B. B. Headache Powder Co. of Georgia, Inc., and relabeled.

6591. Various drugs. (F.D.C. No. 44904. S. Nos. 1–562 R, et al.)

QUANTITY: Unknown quantities of *tablets and capsules of secobarbital sodium, phenobarbital,* and *meprobamate,* and other unidentified prescription drugs, at Rochelle, Ga., in possession of Ronald G. Shawver.

SHIPPED: On unknown dates, from outside the State of Georgia.

LIBELED: 9–26–60, M. Dist. Ga.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and the articles were not exempt from such requirement.

DISPOSITION: 6–1–61. Ronald G. Shawver, claimant, having filed an answer denying that the articles were misbranded and later having requested that such answer be dismissed, which request was allowed, judgment of condemnation was entered and the articles were destroyed.

6592. Mercier's radioactive device. (F.D.C. No. 45456. S. No. 49–319 R.)

QUANTITY: One device at Albuquerque, N. Mex.

SHIPPED: In 1954, from Phoenix, Ariz., by Mercier Laboratories.

LABEL IN PART: "Atomic Energy Applicator Intent of Energy Producing Applicator to Perfect the Chemistry of the Living Substance. Disease Will Disappear in Proportion to the Chemistry Correction."

RESULTS OF INVESTIGATION: The article consisted of a wooden base into which a lead foil-covered cylinder was fitted. In use, a radioactive material was placed in the cylinder between the wire inner wall and the lead foil outer wall. Examination with a Geiger counter showed a reading over the open end of the cylinder of 2.0 milliroentgen units per hour (beta radiations).

LIBELED: 2–2–61, Dist. N. Mex.

CHARGE: 502(a)—when shipped and while held for sale, the label contained false and misleading representations that the article was adequate and effective for perfecting the chemistry of the living substance and for correcting or curing disease conditions; 502(b)(1)—the device failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and 502(f)(1)—the labeling failed to bear adequate directions for use, since the article was worthless for any therapeutic purposes.

DISPOSITION: 3–3–61. Default—destruction.

6593. Harmonizer device. (F.D.C. No. 44421. S. No. 42–508 P.)

QUANTITY: One device at Lynnwood, Wash.

SHIPPED: 10–6–59, from Alhambra, Calif., by C. E. Harmon, D.C., t/a Sound Control Development Co.

LABEL IN PART: "'Harmonizer' Sound Control Development Co. Mach 09 117 Volt Ac 60 Cyl California."

ACCOMPANYING LABELING: Leaflets entitled "Harmonizer Instruction Chart," "Don't Give Up—Wake Up!!," and "Sound Control Development Co. Presents . . . The Harmonizer."

RESULTS OF INVESTIGATION: Examination indicated the device to be a box-shaped, portable cabinet fitted on the front with an instrument panel. The chassis within the cabinet, which consisted of a transformer, tubes, and other electronic components, was connected by an electric cord to the ordinary 110–115 volt house circuit. The unit was purported to be capable of emitting ultrasound, with the instrument panel controlling the "ultrasound frequency," "intensity," "audio-frequency," and "intensity variation." However, the available information indicated that the high and low frequency currents produced in the device were not converted to ultrasound energy.

LIBELED: 4–6–60, W. Dist. Wash.; amended libel 11–18–60.

CHARGE: 501(c)—when shipped, the strength of the device differed from, and its quality fell below, that which it purported to possess since it purported to produce (1) audible sound waves varying from a frequency of 0 to 20,000 cycles per second, and (2) ultrasound waves varying from a frequency of 100,000 to 400,000 cycles per second, whereas the device produced neither sound waves nor ultrasound waves; 502(a)—the labeling contained false and misleading representations that the device was an adequate and effective treatment for arthritis, asthma, sinus trouble, migraine, bursitis, sciatica, neuritis, goiter, epilepsy, prostate trouble, high blood pressure, heart disease, kidney disease, glandular and nerve degeneration, ulcers, cysts, anemia, colitis, osteomyelitis, varicose veins, skin diseases, chronic infections, bronchitis, tumors, and Parkinson's disease; 502(a)—the labeling declared that the device was the "Only Dual unit Sound Therapy for treatment of disease. Composed of Audible (low frequency) and Ultra-Sound controlled vibration," which statement was false and misleading since the device did not provide audible sound or ultrasound therapy and did not produce either audible sound energy or ultrasound energy; 502(a)—the labeling contained false and misleading representations that the device was specific as audible sound therapy for nerve regeneration, increased circulation, tissue repair, and gland and muscle stimulation, whereas the device was not specific or effective as audible sound therapy for such purposes; 502(a)—the labeling contained false and misleading representations that the device was unsurpassed as ultrasound therapy for control of inflammation, elimination of infection, decalcification, tumor disintegration, and pain relief, whereas the device was not effective as ultrasound therapy for such purposes; 502(a)—the labeling contained false and misleading representations that the application of pads of the device to the sinuses, thyroid, anterior and posterior cervicals, mastoid, parotid, submaxillary areas, chest, dorsals, hands, feet, shoulders, elbows, wrists, ankles, knees, arms, legs, viscera, lumbars, sacrum and hips would have therapeutic value as an ultrasonic treatment for disease conditions in those areas whereas the application of the pads to those areas would not have such therapeutic value; 502(a)—the labeling of the device was misleading because it failed to reveal the fact, which was material in the light of the representations which were made therein, that the device, when used as directed, produced only electrical impulses or radio-frequency waves and contained nothing capable of converting such waves to audible sound or ultrasound waves; and 502(f)(1)—the labeling of the device failed to bear adequate directions for use and it was not feasible to devise adequate directions for its use since the article was worthless as audible sound or ultrasound therapy for any medical purpose.

DISPOSITION: On 5–26–60, C. E. Harmon, D.C., and Ned E. Brown filed an answer to the libel denying the allegations of the libel pertaining to misbranding and affirmatively alleging that the device had therapeutic value. The Government filed an amended libel by stipulation with the claimants on 11–18–60. The amended libel added the adulteration charge, amplified the original misbranding charge, and specified two additional leaflets as part of the labeling. On 11–28–60, the Government filed interrogatories which were answered by the claimants in February 1961. Subsequently, without admitting any of the allegations in the amended libel, the claimants withdrew their claim and answer, so that a default decree might be entered.

On 5–5–61, a default decree was filed, in which the court declared that it appeared that the device was misbranded when shipped, because its labeling contained false and misleading representations that the device was an adequate

and effective treatment for a number of diseases and conditions, and because its labeling was false and misleading since the device did not provide audible sound or ultrasound therapy and did not produce audible sound energy or ultrasound energy; and that the device was adulterated when shipped, in that its strength differed from, and its quality fell below, that which it purported to possess since it purported to produce (1) audible sound waves varying from a frequency of 0 to 20,000 cycles per second, and (2) ultrasound waves varying from a frequency of 100,000 to 400,000 cycles per second, whereas the device produced neither sound waves nor ultrasound waves.

The default decree provided for the condemnation of the device and its delivery to the Food and Drug Administration.

DRUG FOR VETERINARY USE

6594. Dr. Bell's Veterinary Medical Wonder. (F.D.C. No. 44912. S. No. 35–675 R.)

QUANTITY: 3,887 individually cartoned bottles at New York, N.Y.

SHIPPED: Between 10–29–59 and 11–27–59, by Juan S. Garcia, Ave. Fdex. Juncos esq. San Andres, Pda. 4, Pta. de Tierra, P.R., San Juan, Puerto Rico, and on 7–11–59, from Kingston, Canada, by Dr. Bell Veterinary Medicine Co.

LABEL IN PART: (Ctn.) "Dr. Bell's Veterinary Medical Wonder * * * Net Contents 15 ml. Dr. Bell Veterinary Medicine Co., Kingston, Ontario, Canada * * * Each ml. contains 0.25 ml. Aconite Fluid Extract; 0.25 ml. Belladonna Root Fluid Extract; 0.25 ml. Digitalis Fluid Extract; 0.1875 ml. Liquid Extract of Nux Vomica."

ACCOMPANYING LABELING: Leaflet in carton entitled "Dr. Bell's VMW Veterinary Medical Wonder."

LIBELED: 10–13–60, S. Dist. N.Y.

CHARGE: 502(a)—when shipped, the following statements contained in its labeling: (carton) "A 'first-aid' treatment for animals suffering the effects of injury, shock, exposure, or sudden illness. As an antispasmodic in nervous conditions. A restorative in exhaustion. * * * In acute cases, such as Colic," (leaflet) "A 'First-Aid' for animals displaying symptoms of Shock, Exposure or Sudden Illness. An Antispasmodic in Nervous Conditions A Restorative in Exhaustion. When veterinary service is not available, administer VMW at the first sign of Coughs, Colic, Pain, Fever, Inflammation, etc. * * * Dosages * * * Calf Scours: * * * Shipping Fever: (Hemorrhagic-Septicemia) When 'shipping fever' symptoms are observed: Difficult breathing, dry painful coughs, arched backs, discharges from nose and eyes, high temperature * * * Colic: * * *," and (bottle) "a 'first-aid' for sick animals * * * colic * * * for shock or exposure," were false and misleading since there was no scientific basis for regarding the article as a first aid for sick animals suffering the effects of sudden illness, shock, injury, or exposure; and the article would not act as an antispasmodic in nervous conditions, or as a restorative in exhaustion; 502(a)—the labeling contained statements which represented and suggested that the article was an adequate treatment for the diseases, conditions, and symptoms referred to therein, which statements were false and misleading since the article was not an adequate treatment for such diseases, conditions, or symptoms; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the conditions and purposes for which it was intended.

DISPOSITION: 2–21–61. Consent—claimed by E. Vadillo Ruiz, Inc., New York, N.Y., and released under bond for export to the original foreign supplier, Dr. Bell Veterinary Medicine Co., Kingston, Canada.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

6595. Elixir of phenobarbital and belladonna. (F.D.C. No. 45301. S. No. 2–739 R.)

QUANTITY: 4 50-gal. drums at Atlanta, Ga.

SHIPPED: 10–18–60, from Greenville, S.C.

LIBELED: 12–21–60, N. Dist. Ga.

CHARGE: 501(a)—contained plant fibers, metallic particles, and whole insects while held for sale.

DISPOSITION: 2–6–61. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS FOR HUMAN USE*

6596. Ferrous sulfate tablets. (F.D.C. No. 45505. S. No. 99–459 R.)

QUANTITY: 53 100-tablet btls. at Gardiner, Maine.

SHIPPED: 11–9–60, from Worcester, Mass., by Buffington's, Inc.

LABEL IN PART: (Btl.) "Entells VIRON * * * Ferrous Sulfate Exsiccated 5 grains. Entells designates Buffington brand Enteric Coated Tablets. Dose: * * * Buffington's Inc. * * * Worcester, Mass."

LIBELED: 3–8–61, Dist. Maine.

CHARGE: 501(b)—when shipped, the article purported to be, and was represented as, *ferrous sulfate tablets*, a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and was represented to be enteric-coated, and its quality fell below the official standard for enteric-coated tablets since the articles failed to meet the disintegration requirements for enteric-coated tablets as provided in the official compendium; and 502(a)—the label statement "Ferrous Sulfate Exsiccated 5 grains" was false and misleading as applied to the article which purported to supply 5 grains of ferrous sulfate in a form assimilable to the body but failed to do so.

DISPOSITION: 3–23–61. Default—destruction.

6597. Cecobee vitamin injectable. (F.D.C. No. 45521. S. No. 14–934 R.)

QUANTITY: 80 ctnd. vials at Cincinnati, Ohio.

SHIPPED: 1–27–61, from Philadelphia, Pa., by Philadelphia Ampoule Laboratories, Inc.

LABEL IN PART: (Bulk ctn.) "20 cc. No. 1109 Multiple Dose Vial B_{12} Plex $\bar{c}$ C A Stable B Complex with B-12 and C Caution: * * * Phila. Ampoule Laboratories Philadelphia 23, Pa. * * * Each cc. contains: * * * Thiamine HCl. 50 mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 70 percent of the declared amount of vitamin B_1.

The article was shipped in bulk cartons of 50 unlabeled vials each and after receipt by the dealer, each vial was labeled and packed in individual cartons.

*See also No. 6593.

LIBELED: 3–15–61, S. Dist. Ohio.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Thiamine HCl. 50 mg." was false and misleading.

DISPOSITION: 4–14–61. Default—destruction.

6598. Vitamin B complex with B_{12}. (F.D.C. No. 45109. S. No. 32–352 R.)

QUANTITY: 518 cartoned vials at Brooklyn, N.Y.

SHIPPED: 8–25–60 and 8–26–60, from Philadelphia, Pa.

RESULTS OF INVESTIGATION: Examination showed that the article contained approximately 17 percent of the declared amount of vitamin B_{12}.

LIBELED: 12–5–60, E. Dist. N.Y.

CHARGE: 501(c)—while held for sale, the strength of the article differed from, and its quality fell below, that which it purported or was represented to possess; and 502(a)—the label statement "Each cc. contains vitamin B-12 30 mcgms." was false and misleading.

DISPOSITION: 3–3–61. Default—destruction.

6599. Hemacombin-P tablets. (F.D.C. No. 45148. S. No. 8–731 R.)

QUANTITY: 2 drums, containing a total of 24,500 tablets, and 5 100-tablet btls., at Rensselaer, N.Y.

SHIPPED: 3–1–60, from Englewood, N.J.

RESULTS OF INVESTIGATION: The article in the bottles had been repacked from bulk stock which had been shipped as described above. Analysis showed that the article contained approximately 73 percent of the declared amount of dextro-amphetamine sulfate.

LIBELED: 11–18–60, N. Dist. N.Y.

CHARGE: 501(c)—while held for sale, the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess; and 502(a)—the label statement "Dextro Amphetamine Sulfate 1.5 mg." was false and misleading.

DISPOSITION: 3–22–61. Default—destruction.

6600. Clinical thermometers. (F.D.C. No. 45414. S. No. 27–398 R.)

QUANTITY: 37 boxes of 12 thermometers mounted on cardboard carriers with 6 thermometers on each carrier, and 2 carriers in each box, at Minneapolis, Minn.

SHIPPED: 12–20–60, from New York, N.Y., by Chase Bottle & Supply Co.

LABEL IN PART: (On thermometer) "Serial Number * * * C. F. Anderson * * * Oral."

RESULTS OF INVESTIGATION: Examination of 24 thermometers showed that 3 failed to meet the requirements for accuracy specified in CS1–52, issued by the National Bureau of Standards of the Department of Commerce, when tested as described in CS1–52; 1 failed to meet the requirement for retreating index as specified in CS1–52; 2 failed to meet the requirements for construction as specified in CS1–52; and 4 had the minor construction defect of having triplicate serial numbers.

LIBELED: 2–9–61, Dist. Minn.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess; and 502(a)—the labeling

of the article contained statements which implied that the article complied with the requirements for accuracy specified in CS1–52, which statements and implications were contrary to fact.

DISPOSITION: 3–28–61. Default—destruction.

6601. Rubber prophylactics. (F.D.C. No. 45401. S. No. 23–994 R.)

QUANTITY: 200 gross ctns. of 12 boxes each at Omaha, Nebr.

SHIPPED: 1–4–61, from North Kansas City, Mo., by Dean Rubber Mfg. Co.

LABEL IN PART: (Box) "One Dozen Peacocks Redi-Wet Rubbers in Foil * * * Dean Rubber Mfg. Co., North Kansas City, Mo. * * * An Aid In Preventing Venereal Diseases. No. 12."

RESULTS OF INVESTIGATION: Examination showed that 1.4 percent of the prophylactics examined were defective in that they contained holes.

LIBELED: 1–19–61, Dist. Nebr.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "An Aid In Preventing Venereal Diseases" was false and misleading as applied to an article containing holes.

DISPOSITION: 4–6–61. Consent—claimed by Dean Rubber Mfg. Co. The court ordered that the article be released under bond for the purpose of destruction except for 5 gross which were to be used by the claimant for testing and research purposes and thereafter destroyed.

DRUGS FOR VETERINARY USE

6602. Medicated feed. (F.D.C. No. 45161. S. No. 25–119 R.)

QUANTITY: 10 50-lb. bags at Concordia, Kans.

SHIPPED: Between 9–16–60 and 9–29–60, from Crete, Nebr., by Crete Mills, Div. of Lauhoff Grain Co.

LABEL IN PART: (Bag) "Victor (For Complete Ration) Pig Starter Medicated For Swine Only * * * Arsanilic Acid 0.008% * * * Manufactured by The Crete Mills, Division of Lauhoff Grain Company, Crete, Nebraska."

LIBELED: On or about 12–28–60, Dist. Kans.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported or was represented to possess; and 502(a)—the label statement "Arsanilic Acid 0.008%" was false and misleading as applied to the article which contained approximately 45 percent of the declared amount of arsanilic acid.

DISPOSITION: 3–2–61. Default—destruction.

6603. Medicated feeds. (F.D.C. No. 45123. S. Nos. 24–089/91 R.)

QUANTITY: 5 50-lb. bags of *egg ration;* 5 50-lb. bags of *Kwickies;* and 131 50-lb. bags of *pig and sow pellets*, at St. Joseph, Mo.

SHIPPED: Between 2–25–60 and 9–20–60, from Nebraska City, Nebr., by G. E. Conkey Co.

LABEL IN PART: (Tag) "Conkeys Y–O Plus Hi–C–50 Complete Commercial Egg Ration Medicated * * * Active Drug Ingredients Furazolidone, 0.011% Oxytetracycline .025 grams per pound," "Conkeys Chlortetracycline (Aureomycin) Mixture * * * Active Drug Ingredient Chlortetracycline (Aureomycin) Hydrochloride .1 gram per lb. * * * Conkeys Kwickies Medicated

* * * Manufactured by G. E. Conkey Co., Nebraska City, Nebraska Pellets"; and (bag) "Y–O Plus * * * Manufactured by G .E. Conkey Co., Nebraska City, Neb. 27% Pig & Sow Pellets * * * Active Drug Ingredient 3-Nitro-4-Hydroxyphenylarsonic Acid .00625%."

RESULTS OF INVESTIGATION: Analyses of the articles showed that *egg ration* contained approximately 3.64 percent of the declared amount of furazolidone, and approximately 19 percent of the declared amount of oxytetracycline; *Kwickies* contained approximately 61 percent of the declared amount of chlortetracycline hydrochloride; *pig and sow pellets* contained approximately 66.56 percent of the declared amount of 3-nitro-4-hydroxyphenylarsonic acid.

LIBELED: 12–1–60, W. Dist. Mo.

CHARGE: 501(c)—when shipped, the strength of the articles differed from that which they purported and were represented to possess.

DISPOSITION: 3–8–61. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

6604. Pearson Sakrin. (F.D.C. No. 43655. S. No. 72–388 P.)

QUANTITY: 99 cases, 36 btls. each, at Atlanta, Ga.

SHIPPED: 9–9–59, from New Providence, N.J., by Pearson Pharmacal Co., Inc.

LABEL IN PART: (Ctn.) "Pearson Sakrin Liquid Sweetener with Exclusive Daramin No Calories! No Sugar! No Salt! No Sodium!" and (btl.) "Pearson Sakrin Super-Concentrated Liquid Sweetener * * * Contents 34 cc."

ACCOMPANYING LABELING: Leaflets in carton reading "The Pearson Sakrin Way to Slimness," and display cartons reading "Lose Weight! Stay Slim! * * * Pearson Sakrin."

LIBELED: 11–5–59, N. Dist. Ga.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for weight reduction or for maintaining slimness.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: On 1–4–60, Pearson Pharmacal Co., Inc., appeared and filed an answer to the libel, a claim to the property, and an application for an order removing the cause to the Southern District of Florida. On 1–18–60, the claimant's motion to remove was overruled and denied by the court in the following opinion:

SLOAN, *District Judge:* "On November 5, 1959, a libel of information was filed against the described property seeking its seizure and condemnation by reason of its allegedly having been misbranded within the meaning of the Federal Food, Drug and Cosmetic Act (21 U.S.C., § 301, et seq.) when introduced into interstate commerce. The articles were subsequently seized under an order of this Court. Pearson Pharmacal Company, Inc., a Florida corporation, on January 4, 1960, filed an answer to the libel and a claim to the property seized.

"Claimant has filed an application for an order removing the cause for trial to the United States District Court for the Southern District of Florida, Miami

*See also Nos. 6582, 6583, 6589, 6592, 6593, 6596–6601.

Division, pursuant to the provisions of 21 U.S.C., § 334. In support of the motion, an affidavit of Lester M. Amster is attached. In this affidavit the affiant deposes that he is president of the claimant corporation and that its principal place of business is 8101 Biscayne Boulevard, Miami, Florida; that claimant does not have or maintain any office within the State of Georgia and that the United States District Court for the Southern District of Florida is within more reasonable proximity to claimant's place of business than is this Court and that a removal of the cause for trial in the United States District Court for the Southern District of Florida at Miami 'would best serve the ends of justice.'

Under Federal Food, Drug and Cosmetic Act provision that, in event of failure of parties to stipulate for removal of condemnation proceeding for trial, a claimant may apply to court of district in which seizure has been made and, absent showing of good cause to contrary, procure order specifying district of 'reasonable proximity' to claimant's principal place of business, such transfer or removal cannot be to district of claimant's principal place of business but only to a 'district of reasonable proximity' thereto. Federal Food, Drug and Cosmetic Act, § 304(a), 21 U.S.C.A. § 334(a).

United States v. United States District Court, 226 F. 2d 238(3).

"The instant motion to remove the case for trial to the district of claimant's principal place of business is overruled and denied."

Subsequently, the claimant moved that its answer and claim be dismissed. On 7–31–61, the claimant's motion to dismiss its answer and claim was granted and a default decree of condemnation and destruction was entered.

6605. Heatex tablets. (F.D.C. No. 45277. S. No. 31–868 R.)

QUANTITY: 3 drums containing a total of 100,000 tablets at Jackson, Miss.

SHIPPED: 8–12–60, from St. Louis, Mo., by K–V Pharmacal Co.

LABEL IN PART: (Drum) "E. C. White Heatex Tablets Each tablet contains: Ascorbic Acid 100 mg. Sea Salt (Admiral Brand) 5 gr. Dextrose 1 gr."

LIBELED: 12–5–60, S. Dist. Miss.

CHARGE: 502(a)—when shipped, the label of the article contained false and misleading representations that the article was adequate and effective to improve mineral nutrition, correct mineral imbalance, and provide energy.

DISPOSITION: 1–31–61. Consent—claimed by Dumas Milner Corp., Jackson, Miss., and relabeled.

6606. Tuff, Colsil #100, and Sil-kol-oid. (F.D.C. No. 45258. S. Nos. 13–791 R, 13–793/4 R.)

QUANTITY: 32 unlabeled bulk drums containing a total of approximately 4,400 lbs. of a light tan-colored crushed rock, commonly called *tuff*, and 112 7-oz. jars of *Colsil #100*, in possession of the Sil-kol-oid Corp., at Butler, Wis.; and 245 7-oz. jars of *Sil-kol-oid* in possession of the Sil-kol-oid Corp., at Wauwatosa, Wis.

SHIPPED: On 11–25–59, 12–17–59, and on previous unknown dates, from Canon City, Colo., by Lamar Ikeler, as a result of arrangements made by Richard Conn, Inc., Columbus, Ohio.

LABEL IN PART: (Jar) "Colsil #100 * * * consists of 100% Activated Colloidal Tuff * * * Richard Conn Incorporated, 1271 E. Broad St., Columbus 5, Ohio" and "Sil-kol-oid * * * Each rounded teaspoonful contains: Refined Calcined Tuff 60 grs. Magnesium Oxide 2 grs. * * * Control Number: 3001 * * * The Sil-kol-oid Corporation, Milwaukee 13, Wisconsin."

RESULTS OF INVESTIGATION: Both the *Colsil #100* and the *Sil-kol-oid* were essentially *tuff*, as stated in their labeling, as follows: "Colsil #100 * * * consists of 100% Activated Colloidal Tuff" and "Sil-kol-oid is an unusual type of naturally occurring multiple mineral colloidal silicates * * * contains micronized colloid forming Tuff * * *." Only color and flavor had been added to *Colsil #100* and color, flavor and magnesium oxide (small quantity) to *Sil-kol-oid*.

LIBELED: 11–30–60, E. Dist. Wis.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representation that the *Sil-kol-oid* (in bulk and in jars) was an adequate and effective treatment for the relief of acid indigestion, sour stomach, heartburn, excessive gas and belching, and was of value in relieving the symptoms of or treating peptic ulcer; and that the *Colsil #100* (in bulk and in jars) was an adequate and effective treatment for calf scours, swine dysentery, bovine coccidiosis, bacterial diarrhea in calves, cows, swine, and sheep.

DISPOSITION: 5–8–61. Consent—destruction.

6607. Salt. (F.D.C. No. 45507. S. No. 50–210 R.)

QUANTITY: 6 ctns., 12 1-lb. cans each, and 20 1-lb. cans, at Denver, Colo.

SHIPPED: 12–20–60, 2–20–61 and 3–1–61, from Sun Valley, Calif., by Salt of the Earth.

LABEL IN PART: (Can) "Natural Organic Salt of the Earth Analysis: Natural Sodium and Chloride 99%; plus 1% organic trace elements, including Calcium, Potassium and Magnesium Salt of the Earth P.O. Box 238, Palm Springs, Calif."

ACCOMPANYING LABELING: Leaflets entitled "What Do You Know About Salt?"

LIBELED: 3–15–61, Dist. Colo.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was "organic" and differed chemically from ordinary commercially available salt; that a patient on a salt-restricted diet may still use the article freely because it differed from ordinary salt; that use of the article instead of ordinary salt would prevent arthritis, heart disease, hardening of the arteries, and calcium deposits in the joints; and that heating salt changes its chemical nature and makes it harmful to the body.

DISPOSITION: 4–28–61. Default—destruction.

6608. Sea brine. (F.D.C. No. 45709. S. No. 46–720 R.)

QUANTITY: 3,120 btls. at Wooster, Ohio.

SHIPPED: 3–2–61 and 3–8–61, from Lakeland, Fla., by Florida Sea Brine Laboratories, Inc.

LABEL IN PART: (Btl.) "8 fl. oz. Sea Brine Concentrated Natural Sea Water Contents This bottle contains 64 drams of highly concentrated 100 percent pure Atlantic Ocean Water. Concentrated 10 times by vacuum evaporation. * * * Concentrated and Bottled by Florida Sea Brine Laboratories, Inc. P.O. Drawer 2435, Lakeland, Florida."

ACCOMPANYING LABELING: Window streamers entitled "We Have Sea Brine"; posters entitled "Contains Natural Minerals and Chemicals * * * Sea Brine * * * Worry Clinic" and "Worry Clinic Drink Sea Water, Crane Recommends"; counter display cards entitled "Now Available * * * Sea Brine" and

"Introductory Offer Sea Brine"; and leaflets entitled "Sea Brine . . . from Ocean to You," "Worry Clinic Sea Water Can Help Prevent Disease, by George W. Crane, Ph. D., M.D.," "Reprinted from the February 5, 1961 issue of the Lakeland Ledger Facts Indicate Ponce De Leon Was On Right Track * * *," "Bottling The Salty Sea," "You Are Invited To Write Dr. Crane * * * Worry Clinic * * * Chemical Smorgasbord vs. Cancer * * *," "Worry Clinic Drink Sea Water, Crane Recommends, By George W. Crane, Ph. D., M.D.," and "Florida Sea Brine Laboratories, Inc., Sea Brine Analysis."

LIBELED: 4–7–61, N. Dist. Ohio.

CHARGE: 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective in the treatment or prevention of cancer, diabetes, multiple sclerosis, leukemia, myasthenia gravis, Parkinson's disease, arthritis, goiter, deficiency ailments, sterility, dental caries, ailments and infections of the eyes, hangover, gray hair, and baldness; that the article provided for rejuvenation, prolonged youth, improved mental health, was adequate and effective in providing for proper function of body glands and organs; and that the article contained significant amounts of essential minerals necessary to health and that such essential minerals are not found in ordinary foods.

DISPOSITION: 5–31–61. Default—destruction.

6609. Vitamin B_{12} injection. (F.D.C. No. 45493. S. Nos. 16–363 R, 62–706/8 R.)

QUANTITY: 52 10-cc. ampules ("No. 627, 100 mcg. per cc."), 12 10-cc. ampules ("No. 569, 30 mcg. per cc."), and 43 5-cc. ampules ("No. 629, 1000 mcg. per cc."), at Cincinnati, Ohio.

SHIPPED: Between 10–18–60 and 1–27–61, from Indianapolis, Ind., by Eli Lilly & Co.

LABEL IN PART: (Ctn.) "Ampoule Injection Betalin 12 Crystalline Vitamin B_{12} Crystalline Injection U.S.P. 100 [or "30" or "1000"] mcg. per cc. * * * Eli Lilly and Company, Indianapolis."

ACCOMPANYING LABELING: Leaflet in each carton entitled "Injection Betalin 12 Crystalline Vitamin B_{12}."

LIBELED: 2–27–61, S. Dist. Ohio.

CHARGE: 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective in the treatment of diabetic and other forms of nutritional peripheral neuritis, trigeminal neuritis, including tic douloureux, herpes zoster, and postherpetic neuralgia, tabes dorsalis, traumatic neuritis, neuritis pain associated with peripheral vascular disorders, osteoarthritis, chronic contact dermatitis, and urticaria.

DISPOSITION: 5–8–61. Default—destruction.

6610. Coldene Vitamin Tonic with Iron. (F.D.C. No. 44918. S. No. 7–501 R.)

QUANTITY: 600 cases of 12 individually cartoned 8-oz. btls. at Norwood, Mass.

SHIPPED: 11–2–59 and 11–3–59, from New York, N.Y., by Mary Scott Rowland, Ltd.

LABEL IN PART: (Btl. and ctn.) "Coldene Vitamin Tonic with Iron * * * giving therapeutic amounts of vitamins important to supplement the diet of those in run-down conditions. Especially indicated for use in convalescence from colds, flu and similar illness. Each fluid oz. (2 Tablespoonfuls) con-

tains: * * * Riboflavin (B_2) 4 mg. * * * Pharma-Craft Corporation, Distrs. Cranbury, N.J."

ACCOMPANYING LABELING: Leaflet in carton entitled "Coldene Liquid Cold Medicine."

RESULTS OF INVESTIGATION: Examination showed that portions of the article contained approximately 70 percent of the declared amount of riboflavin.

LIBELED: 9–26–60, Dist. Mass.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective as a preventive of and treatment for rundown conditions and for use in convalescence from colds, flu and similar ailments; and 502(a)—the name of the article "*Coldene Vitamin Tonic with Iron*" and the label statement "A therapeutic tonic" were false and misleading as applied to a product which was not a vitamin tonic since it contained the vitamin B grouping with methionine and not vitamins in general.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 5–15–61. Consent—destruction.

6611. B_{13} Syrup. (F.D.C. No. 45334. S. No. 30–636 R.)

QUANTITY: 20 btls. at San Antonio, Tex.

SHIPPED: 11–8–57, from St. Louis, Mo.

LABEL IN PART: (Btl.) "One Pint B_{13} Syrup Vitamin B_{12}–B_1 Each 5 cc (1 teaspoonful) contains: Vitamin B_{12} 25 mcg. Vitamin B_1 10 mg."

LIBELED: 1–16–61, W. Dist. Tex.

CHARGE: 502(a)—while held for sale, the bottle label contained statements which represented and suggested that the article would stimulate appetite, promote growth, aid in treating all chronically ill and undernourished children and in the treatment of diarrhea and celiac disease, and that it would shorten all convalescence, which statements were false and misleading, since the article was of no value except in the treatment of vitamin B_1 and vitamin B_{12} deficiencies, conditions which rarely occur; and 502(a)—the name "*B_{13} Syrup*" was false and misleading since it represented and suggested that the article was another of the B complex group of vitamins, which is contrary to fact.

DISPOSITION: 5–3–61. Default—destruction.

6612. Vitamin-mineral capsules. (F.D.C. No. 45122. S. No. 16–784 R.)

QUANTITY: 51 100-capsule btls. and 107 30-capsule btls. at Indianapolis, Ind., in possession of Nacor Medicine Co.

SHIPPED: Between 5–27–60 and 7–28–60, from Newark, N.J., to Lafayette, Ind., and from there to Indianapolis, Ind.

LABEL IN PART: (Btl.) "Nacor-Vite A High Potency Vitamin with Minerals Vitamins A, B_1, B_2, B_6, C and D Plus the Red Vitamin B_{12} and Minerals * * * Distributed by The Nacor Medicine Company, Indianapolis, Ind."

ACCOMPANYING LABELING: Circulars entitled "Can You Banish Those 'Weary Blues' caused by a Nutritional Deficiency?"

RESULTS OF INVESTIGATION: The capsules of the articles were shipped in bulk to Lafayette, Ind., as described above, and after arrival there, were repacked and labeled by the Lafayette Pharmacal, Inc., with labels furnished by the Nacor Medicine Co., and then shipped to Indianapolis, Ind. The above-mentioned circulars were printed locally on order of the Nacor Medicine Co.

LIBELED: 12–20–60, S. Dist. Ind.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of "weary blues," middle age decline, premature aging, loss of vigor after age 35, loss of strength, irritability, depression, excessive fatigue and lack of endurance, nervousness, and rundown conditions; to prolong youthful energy and postpone aging; to feel better, lead more active lives, for better eyesight, sound teeth and bones, mental alertness; to feel stronger, perk up mental powers and think better, for a well-functioning body, pep, buoyant, robust health and healthful vigor; and to boost the blood and revitalize the system.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 27548.

DISPOSITION: 2–13–61. Default—destruction.

6613. Vitest vitamin capsules. (F.D.C. No. 45267. S. No. 2–140 R.)

QUANTITY: 1,089 30-capsule btls. at St. Petersburg, Fla., in possession of Silver Rod Vitamin Co.

SHIPPED: Between 10–15–59 and 8–29–60, from St. Louis, Mo.

LABEL IN PART: (Btl.) "30 Gelets Vitest Vitamin Tested Vitamin Capsules Sugar Free Distributed by Silver Rod Vitamin Co. St. Petersburg 6, Fla. contains 'wonder' citrus bioflavonoids complex a food supplement."

ACCOMPANYING LABELING: Leaflets entitled "Vitest Sugar Free Vitamin Tested Vitamins," "Vitest Vitamin Capsules With CB," "Now New Vitest Capsules," and "How to Start Living and Stop Worrying."

RESULTS OF INVESTIGATION: Upon receipt of the article, the dealer repacked a number of the bottles of the article into shipping containers and placed a number of the above-mentioned leaflets in each container. The leaflets were printed on order of the dealer and used in promoting the sale of the article.

LIBELED: 12–5–60, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of rundown, tired feeling, loss of pep and vitality, premature aging, sterility, muscular dystrophy, loss of appetite, irritability, neuritic pains, loss of interest in important matters, forgetfulness, mouth irritation, skin lesions, intolerance to light, running eyes, skin disorders, gastrointestinal disturbances, diarrhea, fatty deposits in blood vessels, arteriosclerosis, alkalosis, and anemic conditions; to promote good sound health, strengthen the capillaries, feel better and live again, build blood, be more alert, for normal healthy skin and eyes, to promote growth rate and development, build resistance to disease, strengthen the productive faculties, maintain strong blood vessel capillaries, and heal wounds; and, in view of its content of citrus bioflavonoids, that use of the article would result in dramatic curative results in infections, including virus infections that have previously been beyond treatment, and infections that have long defied treatment.

The article was alleged also to be misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 4–3–61. Default—destruction.

6614. Addit "Hi-Vi" Reducing Aid. (F.D.C. No. 45502. S. No. 20–520 R.)

QUANTITY: 62 cases, 24 ctnd. vials each, at Detroit, Mich.

SHIPPED: 4–6–59, from Buffalo, N.Y., by Addit Co.

LABEL IN PART: (Ctn.) "Contents 120 Grams ADDIT 'Hi-Vi' Reducing Aid Multi Vitamin-Mineral Tonic For maintaining vitality while reducing Taken before meals, helps reduce appetite. Distributed by Addit Co., Grosse Pointe 36, Mich."

ACCOMPANYING LABELING: Leaflets in carton entitled "Reducer's Recipes" and "The ADDIT Plan For Reducing For Increasing Vitality For Gaining Weight."

LIBELED: 3–8–61, E. Dist. Mich.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for reducing, maintaining weight, and gaining weight easily, painlessly, and healthfully, while reducing and controlling the appetite, increasing vitality, and preventing nervousness, sleeplessness, and loss of strength; to build up weak, undernourished children, build up strength when rundown, develop resistance to disease, and to restore vigor after debility caused by illness or over-exertion; and that the article was a tonic for those subject to colds and viruses.

The article also was alleged to be misbranded under the provisions of the applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 4–18–61. Default—destruction.

6615. Honey. (F.D.C. No. 44675. S. No. 48–401 R.)

QUANTITY: 1,657 5-gal. cans unlabeled or bearing labels of no significance; 67 5-gal. labeled cans; 292 cases, each containing 12 12-oz. btls.; 166 cases, each containing 6 5-lb. cans; 79 cases, each containing 12 32-oz. jars; 505 cases, each containing 12 16-oz. jars; and 198 cases, each containing 24 8-oz. jars, at Denver, Colo., in possession of Superior Honey Co.

SHIPPED: Between 1–5–60 and 6–22–60, from outside the State of Colorado.

LABEL IN PART: (Can) "Mountain Brand Honey White [or "Light Amber"] Quality" or "Superior Brand Pure Honey"; (btls.) "Pure Honey * * * Superior Honey Co." and "Honey Bear * * * Pure Honey"; (jars) "Superior Brand Honey" and "Superior Cone Honey * * * Southern Style."

ACCOMPANYING LABELING: Books entitled "Folk Medicine A Vermont Doctor's Guide to Good Health, D. C. Jarvis, M.D."

RESULTS OF INVESTIGATION: The article in the labeled cans and in the bottles and jars was repacked by the dealer from bulk stock shipped as described above. The above-mentioned books were used by the dealer in promoting sales of the article.

LIBELED: 7–12–60, Dist. Colo.

CHARGE: 502(a)—while held for sale, the accompanying labeling of the article contained statements which represented and suggested that the article was adequate and effective for the treatment and prevention of arthritis, digestive disorders, belching, constipation, high blood pressure, chronic fatigue, head-

aches, including migraine headache, infectious diseases, including typhoid, bronchopneumonia, peritonitis, pleurisy, and dysentery, fungus diseases, heart disease, diabetes, insomnia, sterility, nervousness, tension, irritability, itching scalp and skin, numbness, cold hands and feet, dizziness, mental retardation, tooth decay, falling hair, breaking fingernails, hay fever, callouses and corns, slow healing of cuts and bruises, pimples, tic, cramps in muscles, blocked and swollen lymph glands, coughs, colds, sinus infection, infant colic, bed-wetting, hangovers, and alcoholism; to provide vigor, promote longevity, control and reduce weight without restrictions of diet; and to reduce or eliminate the difficulties of old age, which statements were false and misleading since the article was not adequate and effective for the treatment and prevention of the diseases, symptoms, and conditions stated and implied and was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: The Superior Honey Co., claimant, filed combined motions to dismiss the libel, to require the government to make the libel more definite and certain, and to strike the misbranding allegations from the libel. On 12–23–60, the court denied the claimant's motions. On 4–27–61, the claimant having denied the allegations of misbranding in the libel but having consented to the entry of a decree, and the court having found that the article was misbranded as alleged, judgment of condemnation was entered. In addition, on the basis of claimant's representations to the court that it had discontinued the distribution of the book "Folk Medicine" at the time of the seizure of the article, and had at no time resumed distribution of the book; that it had no intention to engage in such distribution in Colorado or elsewhere; that it intended to sell its honey products only as a food; that it would not directly or indirectly promote the sale of its honey products through any suggestion that such products were useful in the treatment or prevention of ailments or diseases; and that it had turned over to the United States marshal all copies of the book "Folk Medicine" which it had in its possession, the court ordered that the honey products under seizure be released under bond to be brought into compliance with the law.

6616. Rife Frequency Instrument. (F.D.C. No. 45509. S. No. 17–356 R.)

QUANTITY: 1 device consisting of a variable frequency generator with a controlled power output designated "*Rife Frequency Instrument*" and a frequency counter designated "Model WE–110 Counter R.V.M.I. San Diego, Calif.," at Salt Lake City, Utah.

SHIPPED: 8–1–60, from San Diego, Calif., by Rife Virus Microscope Institute.

ACCOMPANYING LABELING: Four-page printed leaflet entitled "Contract"; two letters signed by John E. Marsh, one dated 9–12–60, and one on the Rife Virus Microscope Institute letterhead dated 7–17–60; and an instruction manual.

RESULTS OF INVESTIGATION: The device was a variable frequency generator with a controlled power output used in conjunction with a Model WE–110 frequency counter. The device included two metal electrodes with insulated handles which were intended to be applied in direct contact with the patient's body.

LIBELED: 3–13–61, Dist. Utah.

CHARGE: 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for devitalizing micro-living organisms detrimental to mankind, and thereby overcoming such conditions as cancer, colds, tumors,

leukemia, athlete's foot, varicose veins, tetanus, typhoid, gonorrhea, staphylococcus, pneumonia, streptothrix, streptococcus, TB virus, carcinoma, sarcoma, treponema, abscess, fistula, hemorrhoids, hernia, irritations, arthritis, bursitis, palsy, diseased lymph nodes, acne, cystitis, boils, bubonic plague, diphtheria, elephantiasis, fungus, impetigo, hardening of the arteries, leprosy, moles, multiple sclerosis, poison oak, poison ivy, poliomyelitis, skin eruptions, spinal meningitis, warts, constipation, typhoid fever, colitis, cataract, glaucoma, leakage of the heart, coronary thrombosis, tetanus, peptic ulcers, and other abnormal and disease conditions.

DISPOSITION: 5–29–61. Default—delivered to the Food and Drug Administration.

6617. Ortho-Structurometer device. (F.D.C. No. 44581. S. No. 44–460 R.)

QUANTITY: One device at Portland, Oreg.

SHIPPED: 4–28–59, from Monrovia, Calif., by Custom Bearings, for J. & E. Enterprises, Inc.

LABEL IN PART: "J. & E. Enterprises, Inc., Model No. Ortho 7 * * * Pasadena, Calif."

ACCOMPANYING LABELING: Leaflets entitled "Self Appraisal" and a posture chart bearing the name "T. E. Hall."

RESULTS OF INVESTIGATION: Examination indicated that the device was a portable unit consisting of two tilt platforms and a control panel for adjusting the platforms to varying degrees. The user stood on the platforms for the intended purpose of changing posture and thereby alleviating various disease and abnormal conditions.

LIBELED: 5–19–60, Dist. Oreg.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for preventing or overcoming prolapsed diaphragm, weakened perineum, rectal prolapse, constipation, hemorrhoids, pudendal hemorrhage, prolapsed uterus, hernia, congested uterus and ovaries, tuberculosis, asthma, heart conditions, bladder irritation, femoral hernia, inguinal hernia, visceral ptosis, broken arches, and ear, eye, nose and throat infections, and that the use of the device would correct improper body mechanics and body imbalance to prevent and overcome most common diseases.

DISPOSITION: On 8–30–60, J. & E. Enterprises, Inc., appeared and filed a claim to the device and, on 8–31–60, the cause was removed to the United States District Court for the Northern District of California. On 9–28–60, the claimant filed an answer denying the misbranding. On 5–1–61, the claim and answer were withdrawn and, on 5–25–61, a default decree of forfeiture was filed and the court ordered the device delivered to the Food and Drug Administration.

6618. Vibra-Finger Gum Massager. (F.D.C. No. 45476. S. No. 26–965 R.)

QUANTITY: 31 individually cartoned devices at Los Angeles, Calif., in possession of Gem Products.

SHIPPED: 1–18–61, from New York, N.Y., by Vibra Research Laboratories.

LABEL IN PART: (Ctn.) "Vibra-Finger Professional Gum Massager * * * Distributors Vibra Research Laboratories."

ACCOMPANYING LABELING: Folder in carton reading in part "Your Vibra Finger Gum Massager Instructions For . . ." and leaflets entitled "Vibra-Finger."

RESULTS OF INVESTIGATION: Examination showed that the article was an electrically operated vibrator device, about the size and general shape of an electric razor. A plastic finger-shaped attachment extended from one end of the motor housing. In use, the vibrating plastic finger attachment was pressed against the gums of the mouth.

The above-mentioned leaflets were printed locally at the request of the dealer and were distributed with the device.

LIBELED: 2–16–61, S. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for promoting strong healthy gums, preventing loosening of teeth, pyorrhea, and soft irritated gums.

DISPOSITION: 4–17–61. Default—destruction.

6619. Health-Aire device. (F.D.C. No. 44721. S. No. 21–425 R.)

QUANTITY: 20 individually cartoned devices at Akron, Ohio.

SHIPPED: 2–15–60, from Long Island City, N.Y., by Samson United of New York.

LABEL IN PART: (Ctn.) "Health Aire for Mountain Air Purity * * * Samson United of New York F 5966."

ACCOMPANYING LABELING: Instruction sheet in carton reading in part "Instruction Sheet For Your Health-Aire" and folder entitled "Samson's Health-Aire."

RESULTS OF INVESTIGATION: The article was a portable cabinet enclosing a fan, a nylon filter, and an ultraviolet lamp. Room air was circulated through the unit which operated on ordinary household electric current.

LIBELED: 7–14–60, N. Dist. Ohio.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for relieving breathing distress and discomfort of allergies, hay fever, asthma, sinus, and colds, and that the article provided health-giving air of "mountain air purity."

DISPOSITION: Samson United Corp. of New York, claimant, having consented to the entry of a decree, judgment of condemnation was entered on 10–14–60, and the court ordered the devices released under bond for relabeling. On 5–2–61, the claimant having failed to file the required bond, the devices were delivered to the Food and Drug Administration.

DRUG FOR VETERINARY USE*

6620. L–K tablets. (F.D.C. No. 45320. S. No. 34–083 R.)

QUANTITY: 6 cases, 12 ctnd. btls. each, at Brooklyn, N.Y.

SHIPPED: During the fall of 1958, from Webster, Mass., by Dr. A. C. Daniels, Inc.

LABEL IN PART: (Ctn.) "Dr. A. C. Daniels L–K Tablets Active Ingredients: Boric Acid, Extract Corn Silk, Extract Hydranges, Extract Buchu, Extract Triticum, Potassium Bicarbonate and Atropine Sulfate 1/2000 grain. Dog–Cat Contents 48 * * * Distributed by Dr. A. C. Daniels, Inc., Boston, Mass. * * * Diuretic. Stimulates the flow of urine. Directions on bottle label."

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*See also Nos. 6594, 6602.

ACCOMPANYING LABELING: Pamphlets entitled "Dr. Daniels 'Easy-Find' Home Care Chart."

LIBELED: 1–12–61, E. Dist. N.Y.

CHARGE: 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for biliousness, torpid liver, and liver jaundice in dogs or cats.

DISPOSITION: 2–9–61. Default—destruction.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 6581 TO 6620

PRODUCTS

[1] (6582, 6591, 6593, 6615, 6617) Seizure contested.

[2] (6581) Injunction issued. Contains opinion of the court, findings of fact, and conclusions of law.

[3] (6604) Seizure contested. Contains opinion of the court.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (6582, 6591, 6593, 6615, 6617) Seizure contested.

[2] (6581) Injunction issued. Contains opinion of the court, findings of fact, and conclusions of law.

[3] (6604) Seizure contested. Contains opinion of the court.

[1] (6582, 6591, 6593, 6615, 6617) Seizure contested.

[2] (6581) Injunction issued. Contains opinion of the court, findings of fact, and conclusions of law.

[3] (6604) Seizure contested. Contains opinion of the court.

U.S. GOVERNMENT PRINTING OFFICE: 1962

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6621-6660

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *July 31, 1962.*

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645600—62

VIOLATIVE SALES OF PRESCRIPTION DRUGS

6621. (F.D.C. No. 45252. S. No. 14–595 R.)

INFORMATION FILED: 6–27–61, S. Dist. Ind., against **Gary W. Menk, Oaktown, Ind.**

CHARGE: On 7–14–60, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: On 8–9–61, this case was transferred to the Western District of Missouri. On 8–24–61, the defendant was sentenced to 1 day in the custody of the Department of Justice.

6622. (F.D.C. No. 45966. S. Nos. 16–080/82 R, 16–084/5 R.)

INFORMATION FILED: 9–8–61, S. Dist. Ohio, against **Norman D. Mayne and William Whitaker, Sharonville, Ohio.**

CHARGE: Between 5–25–60 and 6–10–60, *amphetamine sulfate tablets* were dispensed 3 times and *dextro-amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 9–8–61. Each defendant fined $250, given a sentence of 1 year in jail, which sentence was suspended, and placed on probation for 1 year.

6623. (F.D.C. No. 45965. S. Nos. 16–097 R, 16–103 R.)

INFORMATION FILED: 9–8–61, S. Dist. Ohio, against **Della Carrier and Walter Carrier, Sharonville, Ohio.**

CHARGE: Between 8–8–60 and 9–14–60, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 9–8–61. Walter Carrier was fined $500, given a sentence of 2 years in jail, which sentence was suspended, and placed on probation for 2 years. Della Carrier was given a sentence of 6 months in jail, which sentence was suspended, and placed on probation for 6 months.

6624. (F.D.C. No. 45677. S. Nos. 29–461 R, 53–588 R.)

INFORMATION FILED: 7–28–61, Dist. Minn., against **Donald D. Anderson, t/a Swanson Drug, St. Paul, Minn., and Robert W. Jones (pharmacist).**

CHARGE: On 12–16–60, *capsules containing a mixture of dextro-amphetamine sulfate and amobarbital* were dispensed once without a prescription, and on 12–17–60, *Dexedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9–28–61. Anderson fined $500; Jones fined $200.

6625. (F.D.C. No. 46020. S. Nos. 49–907/8 R.)

INFORMATION FILED: 8–15–61, Dist. N. Mex.; amended information filed 8–29–61, against **Jose Adalberto Munoz, Lordsburg, N. Mex.**

CHARGE: Between 12–17–60 and 12–20–60, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 10–13–61. 6 months in prison.

6626. (F.D.C. No. 45990. S. Nos. 14–926 R, 15–668 R, 15–914/5 R. 15–919 R, 16–416 R, 62–541 R, 62–543 R.)

INFORMATION FILED: 10–27–61, S. Dist. Ohio, against **Mrs. Hazel M. Middleton, t/a Hay-Jo Truck Stop, Morrow, Ohio, Mrs. Jo Anne Blount and Mrs. Helen Hogan (employees).**

CHARGE: Between 5–25–60 and 1–5–61, *amphetamine sulfate tablets* were dispensed 6 times and *dextro-amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty by Mrs. Middleton to all counts; by Mrs. Blount to 2 counts; and by Mrs. Hogan to 2 counts.

DISPOSITION: 10–27–61. Mrs. Middleton—$150 fine, 1 year in prison suspended, and 1 year probation; Mrs. Blount and Mrs. Hogan—1 year in prison suspended and 1 year probation.

6627. (F.D.C. No. 45690. S. Nos. 14–285 R, 15–917 R, 15–929 R, 16–347/8 R, 16–911 R.)

INFORMATION FILED: 7–28–61, S. Dist. Ohio, against **Sheridan C. Bennett, t/a Bennett's Truck Stop, Irwin, Ohio.**

CHARGE: Between 12–30–60 and 7–7–61, *amphetamine sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Guilty.

DISPOSITION: 11–2–61. $750 fine and 3 months in jail. Jail sentence suspended on payment of fine, and probation for 1 year.

6628. (F.D.C. No. 45979. S. Nos. 14–288 R, 15–918 R, 16–415 R, 16–430 R.)

INFORMATION FILED: 7–28–61, S. Dist. Ohio, against **Thomas D. Moffett, Jr., t/a D & J Truck Stop, Marysville, Ohio.**

CHARGE: Between 7–8–60 and 7–27–60, *amphetamine sulfate tablets* were dispensed 4 times without prescription.

PLEA: Guilty.

DISPOSITION: 11–2–61. $500 fine and probation for 1 year.

6629. (F.D.C. No. 45572. S. Nos. 15–916 R, 16–434/5 R.)

INFORMATION FILED: 7–28–61, S. Dist. Ohio, against **Robert E. Wolfe, t/a Bob & Jeans Truck Stop, La Fayette, Ohio.**

CHARGE: Between 7–6–60 and 8–20–60, *amphetamine sulfate tablets* were dispensed twice and *desoxyephedrine hydrochloride tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11–2–61. $500 fine, 3 months in jail suspended, and probation for 1 year.

6630. (F.D.C. No. 45562. S. Nos. 30–849/54 R.)

INFORMATION FILED: 6–14–61, N. Dist. Ala., against **Stephen A. Cruce, t/a Elizabeth Drug Co., Fairfield, Ala.**

CHARGE: Between 5–5–60 and 5–31–60, *amphetamine sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11–27–61. $300 fine.

6631. (F.D.C. No. 44634. S. Nos. 57-065/7 P, 57-069/71 P.)

INFORMATION FILED: 7-12-60, S. Dist. Fla., against **Joseph E. Scott, t/a Chuck Wagon Drive-In, Jacksonville, Fla., and R. C. Kennard.**

CHARGE: Between 8-20-59 and 9-2-59, *amphetamine sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Not guilty to count 6 by Scott; guilty by Kennard to all counts.

DISPOSITION: On 1-8-62, the case against Scott (count 6) came to trial before a jury, and, on 1-9-62, the jury returned a verdict of not guilty. On 1-26-62, Kennard was sentenced to 6 months imprisonment.

6632. (F.D.C. No. 45685. S. Nos. 19-342 R, 46-764/8 R.)

INFORMATION FILED: 7-14-61, E. Dist. Mich., against **Mieczyslaw J. Wieczorek, Detroit, Mich.**

CHARGE: Between 5-4-60 and 4-7-61, *dextro-amphetamine sulfate tablets* were dispensed 5 times and *Achromycin V capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11-13-61. Probation for 2 years.

6633. (F.D.C. No. 45671. S. Nos. 53-018/9 R, 53-593/6 R, 54-132 R.)

INFORMATION FILED: 7-27-61, Dist. Minn., against **Cedar Drug Co. (a partnership), Marvin M. Friedman (partner), Clemence A. Barich (pharmacist employee), Minneapolis, Minn.**

CHARGE: Between 10-21-60 and 11-15-60, *dextro-amphetamine sulfate tablets* were dispensed 5 times and *dextro-amphetamine sulfate with amobarbital tablets* were dispensed twice without a prescription.

PLEA: Guilty by the partnership and Barich to 3 counts; by Friedman to 4 counts.

DISPOSITION: 10-9-61. Cedar Drug Co.—$500 fine; Friedman—$600 fine; Barich—$250 fine.

6634. (F.D.C. No. 45214. S. Nos. 73-581/4 P, 92-313 P.)

INFORMATION FILED: 2-13-61, N. Dist. Ala., against **William W. Bowen, Sr., t/a Bowen's Pharmacy, Birmingham, Ala.**

CHARGE: Between 8-5-59 and 12-17-59, *Benzedrine Sulfate tablets* were dispensed 4 times, and *Tuinal capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 7-31-61. $500 fine.

6635. (F.D.C. No. 45570. S. No. 45-344 R.)

INFORMATION FILED: 5-16-61, N. Dist. Ind., against **Broadway Pharmacy (a partnership), and John Pearson (pharmacist), Gary, Ind.**

CHARGE: On 3-1-60, *Butazolidin tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6-29-61. Pharmacy—$300 fine, plus costs; Pearson—$100 fine.

6636. (F.D.C. No. 45686. S. Nos. 16-653 P, 16-656 P, 80-321/4 P.)

INFORMATION FILED: 5-16-61, N. Dist. Ind., against **Harold S. Blume, t/a Blume Pharmacy, South Bend, Ind.**

CHARGE: Between 3–17–59 and 1–15–60, *Dexamin capsules* were dispensed 5 times and *Butazolidin tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 6–8–61. $500 fine, plus costs.

6637. (F.D.C. No. 45655. S. Nos. 22–561/3 R, 22–565/71 R.)

INFORMATION FILED: 9–25–61, W. Dist. Mo., against **Ira N. Wetherill, t/a Ira Wetherill Drugs, and Homer N. Spence (employee), Independence, Mo.**

CHARGE: Between 6–4–60 and 8–11–60, *Dexedrine Sulfate tablets* were dispensed 7 times and *meprobamate tablets* were dispensed 3 times upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty by Wetherill to all counts; by Spence to 6 counts.

DISPOSITION: 10–27–61. Wetherill—$509 fine; Spence—$105 fine.

6638. (F.D.C. No. 45981. S. Nos. 6–576/8 R, 6–649/50 R, 6–655/6 R, 7–403 R, 7–407/8 R.)

INFORMATION FILED: 8–22–61, Dist. Mass., against **Carl A. Awed, t/a Old Corner Drug, Wollaston, Mass., and also, t/a Savin Hill Pharmacy, Dorchester, Mass.**

CHARGE: Between 4–29–60 and 5–23–60, *Dexedrine Sulfate tablets* were dispensed 4 times upon requests for refills of prescriptions without authorization by the prescriber, and *Equanil tablets*, *Butazolidin tablets*, and *Nembutal capsules* were each dispensed twice without prescription.

PLEA: Guilty.

DISPOSITION: 9–18–61. $1,500 fine, suspended sentence of 1 year and 1 day in jail, and probation for 3 years.

6639. (F.D.C. No. 45547. S. Nos. 49–581/90 P, 76–943/4 P.)

INFORMATION FILED: 6–19–61, W. Dist. Wash., against **Alfred H. Holland and Geloid O. Fulseth (partners in the Liberty Drug Co.), Aberdeen, Wash.**

CHARGE: Between 8–12–59 and 9–23–59, *Dexedrine Sulfate tablets* were dispensed 10 times, and *Achromycin V capsules* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 8–23–61. Each defendant fined $1,000 and placed on probation for 3 years.

6640. (F.D.C. No. 45235. S. No. 27–663 R.)

INFORMATION FILED: 6–13–61, Dist. Minn., against **Charles R. Lindsay, Minneapolis, Minn.**

CHARGE: On 4–16–60, *Dexedrine Sulfate tablets* were dispensed once upon request for prescription refill without authorization from the prescriber.

PLEA: Guilty.

DISPOSITION: 8–2–61. $250 fine.

6641. (F.D.C. No. 45550. S. No. 27–691 R.)

INFORMATION FILED: 7–28–61, Dist. Minn., against **Basil B. Thompson, t/a Thompson Drug Co., Rochester, Minn.**

CHARGE: On 4–21–60, *Dexedrine Spansule capsules* were dispensed once upon request for a prescription refill without authorization from the prescriber.

PLEA: Guilty.

DISPOSITION: 9–28–61. $500 fine.

6642. (F.D.C. No. 45581. S. Nos. 17–920/3 R, 17–927 R.)

INFORMATION FILED: 5–16–61, Dist. Colo., against **Frank Morganari, t/a Dayton Drug, Aurora, Colo.**

CHARGE: Between 6–2–60 and 6–15–60, *Ergoapiol capsules* were dispensed 4 times and *Ergotrate Maleate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 7–21–61. $1,000 fine and probation for 2 years.

6643. (F.D.C. No. 45983. S. Nos. 30–567/72 R.)

INFORMATION FILED: 7–31–61, N. Dist. Ala., against **James W. Goggans, Sylacauga, Ala.**

CHARGE: Between 5–2–60 and 5–28–60, *Equanil tablets* were dispensed 3 times, *Dexedrine Sulfate tablets* were dispensed twice, and *Miltown tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–30–61. $250 fine.

6644. (F.D.C. No. 45545. S. Nos. 2–276 R, 2–279 R, 2–293 R, 2–302 R, 71–965 R.)

INFORMATION FILED: 8–24–61, N. Dist. Ga., against **Walter T. Marks, t/a Thrifty Pharmacy, Atlanta, Ga.**

CHARGE: Between 1–6–60 and 7–18–60, *Equanil tablets* were dispensed 4 times and *Dexedrine Sulfate tablets* were dispensed once upon requests for prescription refills without authorization from the prescriber.

PLEA: Not guilty.

DISPOSITION: On 11–20–61, the case came to trial before the court without a jury. Marks was found guilty on all 5 counts. On 1–15–62, the defendant was sentenced to 1 year in prison on each of 2 counts, to run consecutively, and to 2 years probation on the remaining 3 counts, to begin after serving of the prison sentence.

6645. (F.D.C. No. 45968. S. Nos. 30–551/4 R, 30–579/80 R.)

INFORMATION FILED: 8–16–61, M. Dist. Ala., against **Albert K. Davis, Jr., t/a Davis Drug Co., Montgomery, Ala., and Joseph Vernard Maddox (pharmacist).**

CHARGE: Between 5–21–60 and 6–21–60, *meprobamate tablets* (counts 1, 3, 5, and 6) were dispensed 4 times, and *secobarbital sodium capsules* (counts 2 and 4) were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by Davis to all counts of the information; and by Maddox to counts 2, 4, and 5.

DISPOSITION: 8–30–61. Each defendant placed on probation for 3 years.

6646. (F.D.C. No. 45579. S. Nos. 2–128 R, 2–131 R, 2–135 R, 2–139 R, 2–147/8 R, 2–155 R.)

INFORMATION FILED: 5–19–61, S. Dist. Fla., against **James W. Penuel, t/a Penuel Pharmacy, St. Petersburg, Fla.**

CHARGE: Between 8–25–60 and 11–8–60, *Miltown tablets* were dispensed 7 times upon requests for prescription refills without authorization from the prescriber.

PLEA: Guilty.

DISPOSITION: 6–9–61. $350 fine.

6647. (F.D.C. No. 46010. S. Nos. 45–943 R, 45–982 R, 57–340 R, 59–084 R, 59–090 R, 59–094 R, 59–139 R.)

INFORMATION FILED: 8–16–61, W. Dist. N.C., against **Shamrock Drugs, Inc., and Arthur Melvin Solomon (pharmacist), Charlotte, N.C.**

CHARGE: Between 1–30–61 and 3–17–61, *Miltown tablets* were dispensed 5 times and *Dexedrine Sulfate tablets* were dispensed twice upon requests for prescription refills without authorization from the prescriber.

PLEA: Nolo contendere by the corporation; guilty by Solomon.

DISPOSITION: 10–2–61. Corporation—$500 fine; Solomon—$250 fine.

6648. (F.D.C. No. 45552. S. Nos. 1–675 R, 1–682/3 R, 1–685 R, 1–706 R.)

INFORMATION FILED: 8–24–61, N. Dist. Ga., against **Burnham's Pharmacy, Inc., Hapeville, Ga., and William Otho Burnham (president of the corporation).**

CHARGE: Between 7–6–60 and 10–3–60, *Miltown tablets* were dispensed 5 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 9–14–61. Each defendant placed on probation for 2 years.

6649. (F.D.C. No. 45969. S. Nos. 1–615 R, 1–619/20 R, 1–623/5 R, 3–188 R, 3–196 R.)

INFORMATION FILED: 8–8–61, S. Dist. Ga., against **John C. Williams, t/a Williams Pharmacy, Pearson, Ga.**

CHARGE: Between 11–18–60 and 12–20–60, *Miltown tablets* were dispensed 6 times and *Equanil tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 9–18–61. $350 fine and probation for 2 years.

6650. (F.D.C. No. 43699. S. Nos. 14–872 P, 14–874/8 P.)

INFORMATION FILED: 5–27–60, N. Dist. Ohio, against **Fred C. Bennett, t/a Penn-Art Products, Akron, Ohio, and Margaret Handwerk (employee).**

CHARGE: Between 2–25–58 and 3–17–58, *capsules containing, among other ingredients, phenobarbital* were dispensed 6 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–28–60. Handwerk—3 years probation. 2–2–62. Bennett—2 years probation.

6651. (F.D.C. No. 45963. S. Nos. 70–363/4 R, 70–366 R, 70–378/9 R, 99–565/6 R, 99–595 R, 99–597/600 R.)

INFORMATION FILED: 5–24–61, Dist. Maine, against **George H. Horton, M.D., Bangor, Maine.**

CHARGE: Between 1–10–61 and 4–25–61, *pentobarbital sodium capsules* and *amphetamine sulfate tablets* were each dispensed 6 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–27–61. $5,000 fine, suspended prison sentence of 6 months, and probation for 2 years.

6652. (F.D.C. No. 46363. S. Nos. 51–005 R, 51–007/8 R.)

INFORMATION FILED: 8–15–61, Dist. N. Mex., against **Charles Pray and James F. Parkins (pharmacists), Albuquerque, N. Mex.**

CHARGE: Between 1–15–61 and 1–18–61, *phenobarbital tablets* were dispensed twice and *Benzedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere by Pray to 2 counts; by Parkins to 1 count.

DISPOSITION: 10–31–61. Pray—$200 fine and probation for 1 year; Parkins—$150 fine and probation for 1 year.

6653. (F.D.C. No. 46000. S. No. 18–435/7 R.)

INFORMATION FILED: 8–15–61, Dist. N. Mex., against **Nob Hill Drug, Inc., Albuquerque, N. Mex., and William C. Connell (vice-president).**

CHARGE: Between 3–12–61 and 3–26–61, *phenobarbital tablets* were dispensed twice, and *Benzedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9–7–61. Corporation—$150 fine; Connell—$150 fine and probation for 1 year.

6654. (F.D.C. No. 45665. S. No. 51–008 R.)

INFORMATION FILED: 8–15–61, Dist. N. Mex., against **John Robert "Blackie" Newell, Albuquerque, N. Mex.**

CHARGE: On 1–18–61, *phenobarbital tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12–13–61. 1 year in prison.

6655. (F.D.C. No. 45680. S. Nos. 18–655/6 R, 18–660 R.)

INFORMATION FILED: 6–27–61, Dist. Utah, against **City Pharmacy, Inc., and John William Christensen (president), and Ione Butenhoff (employee), Spanish Fork, Utah.**

CHARGE: Between 9–7–60 and 9–26–60, *penicillin tablets* were dispensed twice without a prescription and *Butazolidin tablets* were dispensed once upon request for a prescription refill without authorization from the prescriber.

PLEA: Guilty by the corporation and by Christensen to all counts; by Ione Butenhoff to 2 counts.

DISPOSITION: 8–30–61. Corporation fined $300; individuals sentenced to 1 year in prison, which was suspended, and placed on probation for 1 year.

6656. (F.D.C. No. 46016. S. Nos. 24–110/1 R.)

INFORMATION FILED: 8–15–61, W. Dist. Mo., against **Joseph Strada, t/a 18th and Troost Pharmacy, and Anthony Cusumano (clerk).**

CHARGE: Between 10–13–60 and 10–18–60, *penicillin tablets* were dispensed twice without a prescription.

PLEA: Nolo contendere by Strada; guilty by Cusumano.

DISPOSITION: On 11–15–61, Strada was fined $200; on 11–16–61, Cusumano was fined $200, plus costs.

6657. (F.D.C. No. 46359. S. Nos. 3–223 R, 3–229 R, 45–899 R, 45–902 R, 45–916 R, 45–929 R, 45–931 R.)

INFORMATION FILED: 8–28–61, M. Dist. Ga., against **Walter L. Minix, t/a Minix Prescription Shop, Moultrie, Ga., and C. Guy Blasingame, Sr. (pharmacist).**

CHARGE: Between 2–23–61 and 4–26–61, *penicillin G potassium tablets* (counts 1, 2, 5, and 7) were dispensed 4 times, *Equanil tablets* were dispensed twice (counts 3 and 6), and *Miltown tablets* (count 4) were dispensed once without a prescription.

PLEA: Nolo contendere by Minix to all counts; by Blasingame to counts 2, 3, 4, 5, and 6.

DISPOSITION: 11–20–61. Minix—$300 fine; Blasingame—$100 fine.

6658. (F.D.C. No. 46008. S. Nos. 45–988 R, 45–998 R, 46–016 R, 59–100 R, 59–121 R, 59–136 R, 59–151 R.)

INFORMATION FILED: 8–8–61, M. Dist. N.C., against **Robert E. Scharff, t/a Clemmons Pharmacy, Clemmons, N.C.**

CHARGE: Between 2–24–61 and 4–10–61, *secobarbital sodium tablets* were dispensed 4 times and *Equanil tablets* were dispensed 3 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 11–6–61. $600 fine and 3 years probation.

6659. (F.D.C. No. 45244. S. Nos. 6–381/5 R.)

INFORMATION FILED: 4–22–61, Dist. Conn., against **William Rosenthal Drug Co., Inc., t/a Si's Prescription Pharmacy, Hartford, Conn., and William Rosenthal (president and treasurer).**

CHARGE: Between 4–8–60 and 5–11–60, *secobarital sodium capsules* were dispensed 3 times upon request for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 12–11–61. Corporation—$300 fine; Rosenthal—60 days imprisonment and 2 years probation.

6660. (F.D.C. No. 45972. S. Nos. 3–282 R, 3–321/6 R.)

INFORMATION FILED: 7–18–61, E. Dist. N.C., against **Steven W. Gowan, t/a Gowan Drug Co., Wallace, N.C.**

CHARGE: Between 4–1–60 and 8–30–60, *meprobamate tablets* were dispensed 3 times and *penicillin tablets* were dispensed twice without a prescription, and *dextro-amphetamine sulfate tablets* were dispensed twice upon requests for refills of prescriptions without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 11–27–61. $500 fine and probation for 2 years.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (6631, 6644) Prosecution contested.

[1] (6631, 6644) Prosecution contested.

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U. S. GOVERNMENT PRINTING OFFICE: 1962

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6661–6700

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve seizure proceedings in which decrees of condemnation were entered after default, or consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *August 13, 1962.*

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 6691, 6694; an imitation of, and sale under name of, another drug, Nos. 6670–6672, 6681; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 6668; cosmetics, actionable under the drug provisions of the Act, Nos. 6691, 6692.

646930—62——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6661–6700

Adulteration, Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from or its quality fell below, that which it purported to possess; Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear, in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(g), the article purported to be a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and it was not labeled as prescribed therein; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency of duration prescribed, recommended, or suggested in the labeling thereof; and Section 502(l), the article was composed wholly or in part of a kind of penicillin, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507.

DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

6661. Hypodermic syringes. (F.D.C. No. 45536. S. No. 3–211 R.)

QUANTITY: 7 ctnd. syringes at Atlanta, Ga.

SHIPPED: 1–9–61, from Long Island City, N.Y., by Propper Mfg. Co., Inc.

LABEL IN PART: (Syringe) "2 cc. * * * 40 Units * * * 80 Units * * * Propper Trophy" and (ctn.) "One 2 cc. Propper TROPHY Hypodermic Syringe Short Insulin 40/80 Propper Mfg. Co., Inc."

ACCOMPANYING LABELING: (Insert leaflet) "Certificate of Accuracy Propper Trophy Hypodermic Syringes. This syringe is made in Japan to conform to standards of accuracy described in Federal Specifications. * * * Propper Mfg. Co., Inc."

RESULTS OF INVESTIGATION: Examination showed the article to be a conventional insulin-type glass hypodermic syringe of 2 cc. size, with graduations marked on one side with a scale reading up to a maximum of 40 units, and marked on the opposite side with a scale reading up to a maximum of 80 units. The syringe was not marked to show that the first scale was to be used for administering insulin from a solution having a potency of 20 units per cubic centimeter, and that the other scale was to be used for administering insulin from a solution having a potency of 40 units per cubic centimeter.

LIBELED: 3–28–61, N. Dist. Ga.

CHARGE: 502(f)(1)—when shipped, the labeling (syringe) failed to bear adequate directions for use of the article as a means of self-administration of insulin; and 502(j)—the article was dangerous to health when used according to the dosage scales inscribed on its label.

DISPOSITION: 6–19–61. Default—destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

6662. Penicillin G potassium tablets. (F.D.C. No. 45896. S. Nos. 83–301/23 R.)

QUANTITY: 578 100-tablet btls. of 50,000 unit *penicillin G potassium tablets* and various drums, cartons and bottles of 50,000, 100,000, 200,000, 250,000, 400,000, and 500,000 unit tablets of penicillin G potassium, totaling 3,369,913 tablets in all, at New York, N.Y., in possession of Pure Laboratories, Inc.

SHIPPED: During 1960 and 1961, from various manufacturers in the State of New York.

RESULTS OF INVESTIGATION: The tablets were repacked by the dealer from *penicillin G potassium tablets* received from various manufacturers who manufactured the tablets from penicillin powder received in interstate commerce.

LIBELED: 5–22–61, S. Dist. N.Y.

CHARGE: 502(l)—while held for sale, the article purported to be a drug composed wholly or in part of penicillin and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507.

DISPOSITION: 6–27–61. Consent—claimed by Pure Laboratories, Inc., and released to be brought into compliance with the law.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6663. Amphetamine sulfate tablets and dextro-amphetamine sulfate tablets. (F.D.C. No. 46116. S. Nos. 31–132/6 R.)

QUANTITY: 2 50,000-tablet drums, 1 btl. of 1,498 tablets, 1 btl. of 2,497 tablets, and 1 can of 6,445 tablets of amphetamine sulfate; 1 btl. of 365 tablets of dextro-amphetamine sulfate, at Mobile, Ala.

SHIPPED: Prior to 7–10–61, from Woodside, Long Island, N.Y., and thereafter transported from Moss Point, Miss., to Mobile, Ala., by Jonathan Mead.

LIBELED: 7–17–61, S. Dist. Ala.

CHARGE: 502(f)(1)—while held for sale by Jonathan Mead, the labeling of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were prescription drugs which were not and would not be lawfully used nor lawfully dispensed by a practitioner licensed by law to administer such drugs in the course of his professional practice.

DISPOSITION: 8–16–61. Default—destruction.

6664. Sea brine. (F.D.C. No. 45845. S. No. 54–441 R.)

QUANTITY: 8 cases of 24 8-oz. btls. each at Minneapolis, Minn.

SHIPPED: 1–18–61, from Lakeland, Fla., by Florida Sea Brine Laboratories, Inc.

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*See also No. 6661.

LABEL IN PART: (Btl.) "100% Pure Atlantic Ocean Water * * * Sea Brine for Better Health * * * Processed and Distributed by the Florida Sea Brine Laboratries, Inc., P.O. Box 1733, Lakeland, Florida."

LIBELED: 6–28–61, Dist. Minn.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was adequate and effective to promote health; and 502(f)(1)—the label failed to bear adequate directions for use since it did not state the condition or conditions for which the article was intended.

DISPOSITION: 8–10–61. Default—destruction.

6665. Sea brine. (F.D.C. No. 45811. S. No. 20–249 R.)

QUANTITY: 20 cases of 12 8-oz. btls. at Saginaw, Mich.

SHIPPED: 5–2–61, from Lakeland, Fla., by Florida Sea Brine Laboratories, Inc.

LABEL IN PART: (Btl.) "Sea Brine * * * Concentrated Natural Sea Water * * * Condimize your Foods and Fruit Juices with Natures own 44 Chemicals of the Sea * * * Concentrated and Bottled by Florida Sea Brine Laboratories, Inc., P.O. Drawer 2435, Lakeland, Florida."

LIBELED: 5–25–61, E. Dist. Mich.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was a complete and balanced salt, supplying chemicals, found only in sea water, which are important to good health and which have therapeutic value; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use, since the label did not state the condition or conditions for which it was intended.

DISPOSITION: 7–24–61. Default—destruction.

6666. Lix-Pain liniment. (F.D.C. No. 45938. S. No. 79–280 R.)

QUANTITY: 12 6-oz. btls. and 15 1-oz. btls. at Washington, D.C., in possession of James L. Guess.

SHIPPED: 2–15–61, from Kinston, N.C., by Oglesby Chemical Co.

LABEL IN PART: "Lix-Pain * * * Cream Liniment * * * Active Ingredients. Ammonium Carbonate, Camphor, Turpentine, Thyme, Lanolin. Caution: * * * Manufactured by Oglesby Chemical Company Kinston, North Carolina."

ACCOMPANYING LABELING: Circulars entitled "What a Few of the Thousands of Users Say About: Lix-Pain" and bearing the mail-order address of the dealer.

LIBELED: 6–6–61, Dist. Columbia.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was adequate and effective as a treatment for swollen joints, swollen glands, arthritis, neuritis, neuralgia, sinusitis, headache, bruises, sprains, minor burns, cramps, toothache, callouses, corns, and bunions; and 502(f)(2)—the labeling failed to warn that the article should be kept out of the reach of children; that use of the article should be discontinued if excessive skin irritation occurs; that for minor arthritis and rheumatic pains the article should not be used by children under 12 years of age and if pain persists for more than 10 days, or redness is present, a physician should be consulted immediately.

DISPOSITION: 7–26–61. Default—destruction.

6667. King's Phylogene powder. (F.D.C. No. 45840. S. No. 31–822 R.)

QUANTITY: 187 btls. at Montgomery, Ala.

SHIPPED: 12–20–60, from Greenville, S.C., by Libby, Edwards & Brown, Inc.

LABEL IN PART: "King's Phylogene Powder 6 Ounces Ingredients: Potassium Alum – Lactose – Zinc Sulfocarbolate and Thymol. Directions: * * * As a Douche * * * Distributed By: King Pharmaceutical Co., Inc., P.O. Box 1925, Montgomery, Ala. 6012089."

LIBELED: 6–15–61, M. Dist. Ala.

CHARGE: 502(f)(2)—when shipped, the labeling of the article failed to bear a warning against use more than twice weekly unless directed by a physician.

DISPOSITION: 6–23–61. Consent—claimed by King Pharmaceutical Co., Inc., and relabeled.

6668. Electronic Magnetic device. (F.D.C. No. 45921. S. No. 57–799 R.)

QUANTITY: 1 device at St. Petersburg, Fla.

SHIPPED: 4–29–60, from Tiffin, Ohio, by L. L. Roby Mfg. Co.

LABEL IN PART: "Electronic Magnetic Model G."

RESULTS OF INVESTIGATION: Examination indicated that the article was a suitcase-type unit which, on opening, displayed a control panel and detector plates. The control panel contained an array of switches, dials, push buttons, electrode terminals, and indicator lights. Electronic components within the case formed a power supply, oscillator, and amplifier for the detection and/or operation of hertzian waves.

LIBELED: 6–2–61, S. Dist. Fla.

CHARGE: 502(b)(1)—when shipped and while held for sale, the device failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use and it was not feasible to devise any directions for use because the article was worthless for any medical purposes.

DISPOSITION: 7–10–61. Default—delivered to the Food and Drug Administration.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

6669. Menodol tablets. (F.D.C. No. 45594. S. No. 35–880 R.)

QUANTITY: 9 cases, each containing 24 50-tablet btls., at Santurce, P.R.

SHIPPED: 10–3–60, from New York, N.Y., by Darro Pharmacal Co., Inc.

LABEL IN PART: (Btl.) "Menodol Improved Each Menodol Tablet Contains: Mephenesin * * * 250 mg. Sodium Salicylate 200 mg. Sodium Gentisate 100 mg. * * * Darro Pharmacal Co., Inc., New York, N.Y. Distributors."

RESULTS OF INVESTIGATION: Analyses showed that the article contained mephenesin, 37 percent; sodium salicylate, 37 percent; and sodium gentisate, 49 percent, of the labeled amount.

LIBELED: 3–24–61, Dist. P.R.

CHARGE: 501(c)—when shipped, the strength and quality of the article fell below that which it purported to possess; and 502(a)—the label statements "Each Menodol Tablet Contains: Mephenesin * * * 250 mg. Sodium Salicylate 200 mg. Sodium Gentisate 100 mg." were false and misleading as

applied to the article which contained less than the declared amounts of such ingredients.

DISPOSITION: 5–29–61. Default—destruction.

6670. Imitation drugs. (F.D.C. No. 45762. S. Nos. 1–549/52 R, 1–554/5 R.)

QUANTITY: 1,700 tablets represented as Dexedrine Sulfate; 1,480 tablets represented as Dexamyl; and 250 tablets represented as Diuril, at Decatur, Ga., in possession of McKinney's Apothecary.

SHIPPED: On unknown dates, from Houston, Tex.

LIBELED: 5–2–61, N. Dist. Ga.

CHARGE: 501(d)(2)—while held for sale, imitation Dexedrine Sulfate, Dexamyl, and Diuril tablets had been substituted for Dexedrine Sulfate, Dexamyl, and Diuril tablets, respectively; 502(a)—the label statements "Dexedrine Tablets 5 mg.," * * * 1000 tablets 5 mg. each Dexedrine Sulfate Smith Kline & French Laboratories * * * T 5265," "Dexedrine tabs * * * Amp. 425 * * * AXDP M," "Dexamyl Tablets 5 mg.," "Diuril 0.5 * * * 1000 tablets * * * Diuril chlorothiazide * * * Merck Sharp & Dohme Division of Merck & Co. * * *," and "Dexamyl Tabs * * * Amt. 425 * * * AERN M" were false and misleading as applied to products which were imitations of such drugs; and 502(i)—the articles were (2) imitations of other drugs and (3) offered for sale under the names of other drugs.

DISPOSITION: 6–19–61. Default—delivered to the Food and Drug Administration.

6671. Imitation Meticorten tablets. (F.D.C. No. 45766. S. No. 59–207 R.)

QUANTITY: 1 btl. containing a total of about 600 tablets at Chicago, Ill., in possession of Accurate Wholesale Drug Corp.

SHIPPED: On an unknown date, from outside the State of Illinois.

LABEL IN PART: (Btl.) "Schering 1,000 Tablets Meticorten (Prednisone) 5 mg. * * * Schering Corporation, Bloomfield, New Jersey, 2146011."

LIBELED: 5–3–61, N. Dist. Ill.

CHARGE: 501(d)(2)—while held for sale, an imitation of Meticorten had been substituted in part for Meticorten; 502(a)—the name "Schering Meticorten (Prednisone)" was false and misleading as applied to a product consisting in part of tablets that were not Schering Meticorten tablets; 502(i)(2)—the article was an imitation of another drug; and 502(i)(3)—the article was offered for sale under the name of another drug, namely, Schering Meticorten tablets.

DISPOSITION: 5–25–61. Default—destruction.

6672. Imitation Serpasil tablets and imitation Equanil tablets. (F.D.C. No. 45763. S. Nos. 26–890 R, 26–893 R.)

QUANTITY: 1 900-tablet btl. of *imitation Serpasil tablets*, and 4 btls. containing a total of about 229 *imitation Equanil tablets*, at Los Angeles, Calif., in possession of Yeilding's Pharmacy.

SHIPPED: During the latter part of 1960 and prior to 4–5–61, from Houston, Tex.

LIBELED: 5–2–61, S. Dist. Calif.

CHARGE: 501(d)(2)—while held for sale, *imitation Serpasil tablets* and *imitation Equanil tablets* had been substituted for Serpasil tablets and Equanil

tablets respectively; 502(a)—the label statements "Serpasil * * * Ciba" and "Equanil * * * Wyeth" were false and misleading as applied to products which were imitations of such drugs; 502(i)(2)—the articles were imitations of other drugs; and 502(i)(3)—the articles were offered for sale under the names of other drugs.

DISPOSITION: 5–26–61. Default—destruction.

6673. **Rubber prophylactics.** (F.D.C. No. 45413. S. No. 53–152 R.)

QUANTITY: 32 1-gross ctns. at N. Kansas City, Mo.

SHIPPED: Between 10–26–60 and 1–10–61, from N. Kansas City, Mo., by Dean Rubber Mfg. Co., to Minneapolis, Minn., and returned to N. Kansas City, Mo., on 1–24–61.

LABEL IN PART: (Ctn.) "Peacocks Reservoir Ends No. 18 Dean Rubber Manufacturing Co., North Kansas City, Mo."

RESULTS OF INVESTIGATION: Examination showed that 3 out of 149 prophylactics examined were defective in that they contained holes.

LIBELED: 2–6–61, W. Dist. Mo.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess.

DISPOSITION: 5–11–61. Default—destruction.

6674. **Rubber prophylactics.** (F.D.C. No. 45751. S. No. 12–997 R.)

QUANTITY: 88 ctns., each containing 144 prophylactics in pkgs., at Streator, Ill.

SHIPPED: 3–9–61, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Spartans Prophylactics Package of Two M & M Rubber Co., K.C., 30, Mo. Sold For The Prevention Of Disease Only."

RESULTS OF INVESTIGATION: Examination of 182 units showed that 3 were defective in that they contained holes.

LIBELED: 4–28–61, N. Dist. Ill.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold For The Prevention of Disease Only" was false and misleading as applied to an article containing holes.

DISPOSITION: 5–25–61. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

6675. **Various vitamin products.** (F.D.C. No. 45922. S. Nos. 55–752/60 R.)

QUANTITY: 1,455 100-tablet btls. of *multiple vitamin tablets;* 1,329 100-tablet btls. of 100 mg. *vitamin C tablets;* 555 100-tablet btls. of 250 mg. *vitamin C tablets;* 159 100-capsule btls. of *vitamin E capsules;* 393 100-tablet btls. of *vitamin B_1 tablets;* 156 144-tablet btls. of *Magnivil tablets;* 141 250-tablet btls. and 288 100-tablet btls. of *Daily Ration with Minerals tablets;* 141 100-tablet btls. and 132 250-tablet btls. of *Soluvil Ovalettes tablets;* 189 100-tablet btls. and 156 250-tablet btls. of *Daily Ration Multiple Vitamins tablets,* at Seattle, Wash.

SHIPPED: Prior to 9–1–60 and between 10–3–60 and 3–30–61, from Dallas, Tex., by Preston-National Drug Co.

*See also Nos. 6664–6666, 6669–6672, 6674.

LABEL IN PART: Labels which each read "Worthall * * * Marketime Drugs" as well as "Multiple Vitamins for adults and children"; "Vitamin 'C' Ascorbic Acid U.S.P. 100.0 mg."; "Vitamin 'C' Ascorbic Acid U.S.P. 250.0 mg."; "Vitamin 'E' 100 I.U."; or "Vitamin 'B–1' Thamin HCl 100.0 mg. 33,330 U.S.P. Units"; and labels which each read "Preston-National * * * Preston-National Drug Co., Dallas," as well as "Magnivil Vitamins and Minerals with B_{12}"; "Daily Ration with Minerals A Multiple Vitamin & Mineral Formula for Adults & Children"; "Soluvil Ovalettes Multiple Vitamins with 'B–12' and 'E' in Delicious Chewable Form"; or "Daily Ration Multiple Vitamins For Adults & Children."

ACCOMPANYING LABELING: Leaflets entitled "The Vitamins What They Are What They Do For You"; "Comparison Chart Magnivil"; and "Comparison Chart Daily Ration."

RESULTS OF INVESTIGATION: The accompanying labeling had been shipped to the dealer by Preston-National Drug Co., and had been used by the dealer in promoting sales of the articles.

LIBELED: 6–6–61, W. Dist. Wash.

CHARGE: *Multiple vitamin tablets*, 502(a)—when shipped and while held for sale, the leaflet, entitled "The Vitamins What They Are What They Do For You," accompanying the article, contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of colds and other infectious diseases; nervousness; neuritis; loss of reflexes; skin disorders; inadequate growth; anemia; scalp disorders; faulty digestion and blood circulation; liver disease; irritability; gastrointestinal disorders; and swollen joints;

Vitamin C tablets (100 mg. and 250 mg.), 502(a)—the leaflet, entitled "The Vitamins What They Are What They Do For You," accompanying the article, contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of colds; heat prostration; tender, bleeding gums; loosening of teeth; slow healing of wounds; and painful and swollen joints;

Vitamin E capsules, 502(a)—the leaflet, entitled "The Vitamins What They Are What They Do For You," accompanying the article, contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of sterility; heart trouble; aching joints; improper mobility of joints; and arthritis;

Vitamin B_1 tablets, 502(a)—the leaflet, entitled "The Vitamins What They Are What They Do For You," accompanying the article, contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of nervousness; neuritis; improper appetite and digestion; inadequate energy; loss of reflexes; abnormal blood pressure; and to minimize the effects of alcoholic overindulgence;

Magnivil tablets, 502(a)—the leaflets, entitled "Comparison Chart Magnivil" and "The Vitamins What They Are What They Do For You," accompanying the article, contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of sterility; heart trouble; arthritis; insomnia; constipation; indigestion; colds and other infectious diseases; nervousness and neuritis; loss of reflexes; skin disorders; faulty digestion and blood circulation; and liver diseases;

Daily Ration tablets, 502(a)—the leaflets, entitled "Comparison Chart Daily Ration" and "The Vitamins What They Are What They Do For

You," accompanying the article, contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of colds and other infectious diseases; nervousness; neuritis; loss of reflexes; skin disorders; inadequate growth; anemia; scalp disorders; faulty digestion and blood circulation; liver disease; gastrointestinal disorders; and swollen joints; and

Soluvil Ovalettes tablets, 502(a)—the leaflet, entitled "The Vitamins What They Are What They Do For You," accompanying the article, contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of colds and other infectious diseases; nervousness; neuritis; loss of reflexes; skin disorders; inadequate growth; anemia; scalp disorders; faulty digestion and blood circulation; liver disease; gastrointestinal disorders; swollen joints; sterility; heart trouble; and arthritis.

DISPOSITION: 7–27–61. Consent—claimed by the shipper and released under bond to be brought into compliance with the law.

6676. Tafco vitamin tablets. (F.D.C. No. 45513. S. Nos. 61–081/3 R.)

QUANTITY: 32 btls. of Tafco vitamin C tablets, 218 100-tablet btls. of Tafco geriatric type tablets, and 234 100-tablet btls. of Tafco therapeutic type tablets, at Wichita, Kans., in possession of Tafco Products.

SHIPPED: 5–6–60 and 5–25–60, from St. Louis, Mo.

LABEL IN PART: (Btl.) "Vitamin C Compressed Tablet Each tablet contains: Vitamin C (Ascorbic Acid) 100 mg. (Lemon Flavored) * * * Dose: * * * Manufactured for Tafco Products, 3350 S. Osage, Wichita, Kansas"; "Tafco Geriatric type tablet with Choline Inositol and Methionine Manufactured for Tafco Products, 3350 S. Osage Wichita, Kansas * * * Each tablet contains: * * * Vitamin E * * * Dl-Methionine * * * **Need has not been established" and "Tafco Therapeutic Type Tablets * * * Manufactured for Tafco Products * * * Each tablet contains: * * * Dl-Methionine * * * Vitamin E * * * **Need has not been established."

ACCOMPANYING LABELING: Leaflets entitled "Tafco * * * Lemon Flavored Vitamin C Wafers As An Aid In Building Body Resistance" and "Tafco Food Supplements from Nature's Laboratory"; and price list entitled "Tafco-Vita."

RESULTS OF INVESTIGATION: The leaflets and price list were prepared by the dealer and were used in promoting sales of the articles.

LIBELED: 3–22–61, Dist. Kans.

CHARGE: Vitamin C tablets, 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of infectious diseases; cold and flu symptoms; muscular aches and pains; virus infections which cause upset stomach and nausea; circulatory disorders, arteriosclerosis, anemia; hemorrhoids; conditions resulting from stress; pruritus; dermatitis; poison ivy and poison oak; bleeding, sore, and spongy gums; loosening of teeth; improper blood formation; allergies and hay fever; and to build body resistance; neutralize toxins; control cholesterol in the blood and prevent heart disease; and stimulate production of cortisone; and that less than 10 percent of adults have optimal levels of vitamin C and 90 percent of the population needs to supplement the diet with vitamin C; that most children,

and practically all adults, are deficient in vitamin C; and that smoking one cigarette will neutralize 15 times the daily requirement for vitamin C.

Therapeutic type tablets, 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of improper gland functioning; hard, fatty deposits called cholesterol which block kidney and liver passages, blood vessels, and arteries; and that the vitamin B complex in the article would correct bad eating habits; and that the article contained a significant amount of lipotropic factors for special dietary use and therapeutic purposes.

Therapeutic type and geriatric type tablets, 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the articles were adequate and effective as a treatment for and preventive of conjunctivitis; erosion of eye tissues and clouding of cornea; infections; neuritis; pernicious anemia; sterility; to promote vitality and well-being; sound health; and normal vision and eye health; and that all ingredients of the articles were as they exist in nature, and that by consuming the articles maximum nutrition would result.

The libel alleged also that the therapeutic type tablets and the geriatric type tablets were misbranded under the provisions of the Act relating to food as reported in notices of judgment on foods, No. 27850.

DISPOSITION: 6–1–61. Default—destruction.

6677. Vitamin capsules. (F.D.C. No. 45780. S. Nos. 61–052/4 R.)

QUANTITY: 44 50-capsule btls. and 110 100-capsule btls. of multiple vitamin capsules; 139 100-capsule btls. and 70 200-capsule btls. of vitamin B complex capsules; and 104 200-capsule btls. and 4 100-capsule btls. of vitamin A capsules, at Dubuque, Iowa, in possession of B. A. Ruegnitz Laboratories.

SHIPPED: 2–16–61 (multiple vitamins and vitamin B complex) and on an unknown date (vitamin A), from Detroit, Mich.

LABEL IN PART: "Ruegnitz Multiple Vitamin Capsules * * * Dose: * * * Contents * * * Distributed by B. A. Ruegnitz Laboratories, Dubuque, Iowa * * * 61F Dubuqueland's Vitamin Center"; "Hi Vitamin B Complex Contents * * * Distributed by B. A. Ruegnitz Laboratories, Dubuque, Iowa Each Capsule Contains * * * 61F Directions:"; and "Hi Vitamin A 25,000 units per capsule Contents * * * Distributed by B. A. Ruegnitz Laboratories Dubuque, Iowa Directions."

ACCOMPANYING LABELING: Leaflets entitled "Everyone Needs These High Potency Vitamins," "B. A. Ruegnitz Laboratories * * * Thank you for your inquiry," and "Interesting Information You May Want To Know About Ruegnitz Vitamins."

RESULTS OF INVESTIGATION: The capsules were shipped in bulk and repacked and labeled by the dealer. The leaflets were also prepared by the dealer and used in promoting sales of the articles.

LIBELED: 5–4–61, N. Dist. Iowa.

CHARGE: While held for sale, all articles, 502(a)—the accompanying labeling contained false and misleading representations that the articles were adequate and effective as a treatment for and preventive of colds, sinus trouble, tired, run-down conditions, lack of pep and energy, nervousness, depressed condition, chronic fatigue, poor appetite, disease and infection, and to relieve tension, as well as other diseases and conditions; and that, due to storage conditions, sea-

sonal scarcities, excessive cooking, refinery methods, and eating habits, everyone is obtaining an insufficient amount of vitamins from the diet and requires vitamin supplementation.

Multiple vitamins and vitamin B complex, 502(a)—the accompanying labeling contained false and misleading representations that the articles were adequate and effective as a treatment for and preventive of neuritis, loss of reflexes in extremities, abnormal blood pressure, skin and scalp disorders, anemia, and improper blood circulation.

Multiple vitamins and vitamin A, 502(a)—the accompanying labeling contained false and misleading representations that the articles were adequate and effective as a treatment for and preventive of poor, weak vision.

DISPOSITION: 6–15–61. Consent—claimed by B. A. Ruegnitz Laboratories and released for relabeling.

6678. Revco vitamin capsules and tablets. (F.D.C. No. 45522. S. Nos. 62–687/93 R.)

QUANTITY: 24 100-capsule btls. of vitamin A (25,000 U.S.P. units); 63 100-capsule btls. of vitamin A (50,000 U.S.P. units); 75 100-tablet btls. of vitamin C (250 mg.); 56 100-tablet btls. of vitamin C (100 mg.); 35 100-tablet btls. of vitamin E; 25 100-tablet btls. of Formula 101; and 1 100-tablet btl. of Formula 202, at Cincinnati, Ohio.

SHIPPED: Between 1–26–61 and 3–11–61, from Detroit, Mich., by Regal Drug Co.

LABEL IN PART: (Btl.) "Registered Vitamins REVCO * * * Vitamin A (Natural) 25,000 [or "50,000"] U.S.P. Units Registered Vitamin Corp. Detroit 11, Michigan. Distributors * * * Research Testing Scientific Associates Quality Control * * * Control No. 11658 [or "11659"]"; "Registered Vitamins REVCO * * * Vitamin C 250 mg. [or "100 mg."] Research Testing Scientific Associates Quality Control * * * Control No. 12028 [or "11954"]"; "Registered Vitamins REVCO * * * Non-Oily Vitamin E 100 International Units Registered Vitamin Corp. Detroit, Michigan Distributors * * * Control No. 12063"; "Registered Vitamins REVCO * * * Formula 101 [or "Formula 202"] Vitamins & Minerals for Young Adults [or "the Middle Years"]. Registered Vitamin Corp. Detroit 11, Michigan—Distributors * * * Control No. 10708 [or "10942"]."

ACCOMPANYING LABELING: (Newspaper-type price lists) "Cold, Changeable Weather Increases Your Need for Vitamins & Minerals * * * Revco Vitamins Give You . . ." and display placards for the articles "Revco 101" and "Revco 202."

LIBELED: 3–20–61, S. Dist. Ohio.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that vitamin A was adequate and effective as a treatment for and preventive of infections, low resistance to infections, retarded growth, loss of vigor, and to promote growth and vitality necessary for reproduction; that vitamin C was adequate and effective as a treatment for and preventive of improper formation of bones and teeth, tooth decay, and hemorrhage and muscular weakness; that vitamin E was adequate and effective as a treatment for and preventive of sterility, muscular dystrophy, and failure of reproduction; that Formula 101 was adequate and effective as a treatment for and preventive of nervousness, irritability, colds, tiredness, conditions resulting from being over-worked and worried and from tension, to promote pep and energy, and to maintain healthy skin, hair, and nails; and

that Formula 202 was adequate and effective as a treatment for and preventive of tensions, sensitivity to noise, loss of morale, irritability, digestive upsets, gas discomforts, heartburn, low resistance, nervousness, cholesterol deposits in blood vessels, and to provide energy and vitality, promote intellectual capacities, strengthen nerve tissues, promote rich, red blood, maintain endurance, and promote the metabolism of fats.

The libel alleged also that the articles Formula 101 and Formula 202 were misbranded under the provisions of the Act relating to food, as reported in notices of judgment on foods.

DISPOSITION: 5–17–61. Consent—claimed by Cinci Vitamin & Cosmetic Distributors, Inc., Cincinnati, Ohio. The accompanying literature was destroyed and the tablets and capsules were released to the claimant for relabeling. The Formula 101 and Formula 202 tablets were destroyed on 7–3–61, by claimant.

6679. Becevit tablets. (F.D.C. No. 45704. S. No. 67–333 R.)

QUANTITY: 150 100-tablet btls. at Fort Worth, Tex.

SHIPPED: 8–4–60, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "Becevit Therapeutic B-Complex with Vitamin C and Hesperidin Each Tablet Contains: %MDR Vitamin B–1 15 mg. 1500 Vitamin B–2 10 mg. 833 Vitamin B–6 5 mg. * * Vitamin C 250 mg. 750 Calcium Pantothenate 10 mg. * Hesperidin Purified 20 mg. * * Niacinamide 50 mg. 500 *—The daily adult requirement has not been established. * *—The need for * * * in human nutrition * * * not established. Coral Laboratories Pharmaceuticals Dist. Co. Fort Worth, Texas."

ACCOMPANYING LABELING: Detail cards reading in part "Becevite * * * Indications."

RESULTS OF INVESTIGATION: Investigation showed that the detail cards were printed locally on the order of the dealer, Coral Laboratories, Fort Worth, Tex.

LIBELED: 4–14–61, N. Dist. Tex.

CHARGE: 502(a)—while held for sale, the labeling (detail cards) contained false and misleading representations that the article was adequate and effective in hastening wound healing in pre- and post-surgical cases, in second- and third-degree burns, and in peptic ulcers; and the label statement "Each Tablet contains . . . Hesperidin Purified – 20 mg." was false and misleading since such ingredient would be of insignificant value for the effects claimed in the labeling of the article.

DISPOSITION: 5–25–61. Consent—claimed by Coral Laboratories and relabeled. Accompanying labeling destroyed.

6680. Coldene vitamin tonic with iron. (F.D.C. No. 45882. S. No. 35–812 R.)

QUANTITY: 15,600 individually ctnd. btls. at Brooklyn, N.Y.

SHIPPED: 11–30–59, from Chicago, Ill., by Sanco Drug Co.

LABEL IN PART: (Btl. and ctn.) "Coldene Vitamin Tonic with Iron * * * Each fluid oz. (2 Tablespoonfuls) contains: * * * Riboflavin (B_2) 4 mg. * * * Pharma-Craft Corporation, Distrs. Cranbury, N.J."

ACCOMPANYING LABELING: Leaflet in carton entitled "Coldene Liquid Cold Medicine."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 68 percent of the declared amount of riboflavin.

LIBELED: 5–12–61, E. Dist. N.Y.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was adequate and effective for the prevention of and treatment for rundown conditions; and for use in convalescence from colds, flu, and similar illness; and the name of the article "*Coldene Vitamin Tonic With Iron*" and the label statement "therapeutic tonic" were misleading since the article was not adequate and effective as a "Vitamin Tonic," since it contained the vitamin B grouping and methionine, not vitamins in general.

The libel alleged also that the article was adulterated and misbranded under the provisions of the Act relating to foods, as reported in notices of judgment on foods.

DISPOSITION: 6–8–61. Default—destruction.

6681. Reserpine tablets. (F.D.C. No. 45488. S. Nos. 4–701 R, 4–704 R.)

QUANTITY: 1 btl. containing approximately 500 white tablets with "CIBA" embossed on one side at Alexandria, Va.

SHIPPED: The article was a commingled lot which had been shipped, in part, prior to 2–9–61, from Hillcrest Heights, Md., and, in part, on 6–3–60, from Summit, N.J.

LABEL IN PART: (Btl.) "1000 Tablets * * * Serpasil Brand of Reserpine U.S.P. 0.25 mg."

RESULTS OF INVESTIGATION: Analysis showed the tablets to be, in part, counterfeits of Serpasil tablets.

LIBELED: 2–17–61, E. Dist. Va.

CHARGE: 502(a)—when shipped, the name of the article "Serpasil" was false and misleading as applied to a product which was in part an imitation of "Serpasil"; and 502(i)—the tablets were (2), in part, an imitation of another drug and (3), in part, offered for sale under the name of another drug.

DISPOSITION: 7–6–61. Default—destruction.

6682. Sea-Min. (F.D.C. No. 45874. S. No. 14–320 R.)

QUANTITY: 16 1-gal. btls. and 17 1-pt. btls. at Grove City, Ohio, in possession of Sea-Min Co. (Mark H. Jones).

SHIPPED: In December 1960, from the vicinity of Asbury Park, N.J., by Mark H. Jones.

LABEL IN PART: (Pint btl.) "Sea-Min A Specially Prepared Concentration From The Sea. Minerals in Sea Water Normally Contain 44 Trace Elements as Listed Hereon. * * * Sea-Min Co. P.O. Box 391 Grove City, Ohio."

RESULTS OF INVESTIGATION: The water was taken from the Atlantic Ocean and prepared and bottled by the dealer.

LIBELED: On or about 5–8–61, S. Dist. Ohio.

CHARGE: 502(a)—when shipped and while held for sale, the label contained false and misleading representations that the article contained nutritionally significant amounts of essential minerals, and that all of the elements contained in the article are necessary for health.

DISPOSITION: 6–13–61. Default—destruction.

6683. Sea brine. (F.D.C. No. 45735. S. No. 67–328 R.)

QUANTITY: 114 btls. at Dallas, Tex.

SHIPPED: On an unknown date, from Lakeland, Fla., by Florida Sea Brine Laboratories, Inc., to Minneapolis, Minn.; reshipped, on 1-23-61, from Minneapolis, Minn., to Dallas, Tex.

LABEL IN PART: (Btl.) "This Bottle Contains 64 Drams of highly concentrated 100% pure Atlantic Ocean water 8 fl. oz. Sea Brine for better health Recommended dosage for ages 9 to 109 — 1 teaspoon per day * * * Use like seasoning in cooked foods. Contains Chloride, Sodium, Sulfate, Magnesium, Calcium, Potassium. Salt free Dietetics consult your doctor before using * * * Processed and distributed by The Florida Sea Brine Laboratories, Inc., P.O. Box 1733 Lakeland, Florida."

ACCOMPANYING LABELING: Leaflets entitled "Worry Clinic Drink Sea Water, Crane Recommends."

RESULTS OF INVESTIGATION: The leaflets were shipped by the above-named shipper, on 12–31–60, from Florida to Texas, by parcel post.

LIBELED: 5–9–61, N. Dist. Tex.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was adequate and effective in the treatment or prevention of cancer, diabetes, leukemia, gray hair, baldness, multiple sclerosis, myasthenia gravis, sterility, Parkinson's disease, arthritis, goiter, deficiency ailments, and dental caries; that the article was a "chemical smorgasbord" for body glands, thereby providing for the proper function of the pancreas, liver, spleen, bone marrow, thyroid, adrenals, and other organs to guard health and prevent sickness; that through use of the article one may achieve better health; that our foods, as consumed, fail to provide sufficient quantities of essential minerals; and that sufficient quantities of these essential minerals were supplied by the article.

DISPOSITION: 6–19–61. Default—delivered to the Food and Drug Administration.

6684. Sea brine. (F.D.C. No. 45726. S. No. 43–147 R.)

QUANTITY: 48 btls. at San Jose, Calif.

SHIPPED: 2–7–61, from Lakeland, Fla., by Florida Sea Brine Laboratories, Inc.

LABEL IN PART: (Btl.) "Sea Brine Concentrated Natural Sea Water * * * This bottle contains 64 grams of highly concentrated 100 per cent pure Atlantic Ocean Water. Concentrated 10 times by vacuum evaporation. 64-day Supply One teaspoon per day to be added to fruit juice or vegetables or taken with regular tap water. The Salty Flavor may be used as a seasoning in cooked foods. * * * Concentrated and Bottled by Florida Sea Brine Laboratories, Inc. P.O. Drawer 2435 Lakeland, Florida."

ACCOMPANYING LABELING: Leaflets entitled "Sea Water Can Help Prevent Disease, by George W. Crane, Ph. D., M.D."; posters entitled "Bottling the Salty Sea" and "Drink Sea Water, Crane Recommends."

LIBELED: 5–3–61, N. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was adequate and effective as a treatment for deficiency ailments, cancer, diabetes, gray hair and baldness, complaints not due to germs or a virus, arthritis, multiple sclerosis, myasthenia gravis, Parkinson's disease, leukemia, sterility, dental caries, as an "antidote for disease," for prolonging life, promoting better health, "condi-

tions" and infections of the eye, hangover, and was a "fountain of youth"; that the article was significant as a "chemical smorgasbord" for body glands enabling them to perform their natural function; and that foods, as consumed, are lacking in all the trace minerals that are found in the article.

DISPOSITION: 6–26–61. Default—destruction.

6685. **Concentrated ocean water.** (F.D.C. No. 45786. S. No. 20–261 R.)

QUANTITY: 369 8-oz. btls. at Saginaw, Mich.

SHIPPED: In February 1961, from the vicinity of Bradenton, Fla., by William D. Kelly.

LABEL IN PART: (Btl.) "Concentrated Ocean Water 100 Percent Pure Contains Over 40 Minerals The Normal Body Requires. Recommended Dosage for Young and Old * * * Distributed by Mr. and Mrs. W. D. Kelly Copartners, 921 North Mason Street Saginaw Michigan."

RESULTS OF INVESTIGATION: The water was taken from the Gulf of Mexico and prepared and bottled by the dealers.

LIBELED: 5–3–61, E. Dist. Mich.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article contained sufficient quantities of essential minerals to be of therapeutic value.

DISPOSITION: 6–21–61. Default—destruction.

6686. **Lem-O-C Wafers.** (F.D.C. No. 45890. S. No. 53–566 R.)

QUANTITY: 180 250-wafer btls. at Minneapolis, Minn.

SHIPPED: 3–17–61, from St. Louis, Mo., by Private Formulae, Inc.

LABEL IN PART: "Lem-O-C Lemon Flavored Chewable Vitamin Candy Wafer Vitamin C 100 mg. 333% MDR * * * Nu-Age Corporation, Box 5816, Minneapolis 19, Minn."

LIBELED: 5–17–61, Dist. Minn.

CHARGE: 502(a)—when shipped, the label statement "Helps Build resistance to Colds – Sinus Conditions – Allergies – Tooth Decay – Hay Fever" was false and misleading since the article was not effective for such purposes.

The libel alleged also that the article was misbranded under the provisions of the Act relating to foods, as reported in notices of judgment on foods.

DISPOSITION: 6–29–61. Default—destruction.

6687. **Sumtal Antacid Wafers.** (F.D.C. No. 45613. S. Nos. 51–814/5 R.)

QUANTITY: 23 cases, each containing 12 42-tablet btls., and 1 case containing 12 168-tablet btls., at Salt Lake City, Utah, in possession of Howell Pharmacal Co.

SHIPPED: 1–23–59, from Culver City, Calif., by Diketan Laboratories, Inc.

LABEL IN PART: (Btl.) "Sumtal Antacid Wafers Howell Pharmacal Co. Dist. Salt Lake City, Utah."

ACCOMPANYING LABELING: File cards entitled "Sumtal Wafers & Liquid."

RESULTS OF INVESTIGATION: The file cards were prepared by the dealer and used in promoting sales of the article.

LIBELED: 4–7–61, Dist. Utah.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was an adequate and effective treatment for gastric and duodenal ulcers.

DISPOSITION: 6–27–61. Default—destruction.

6688. Ulcertrol. (F.D.C. No. 45713. S. No. 20–189 R.)

QUANTITY: 45 btls. at White Pigeon, Mich., in possession of Red's Market; 12 btls. at White Pigeon, Mich., in possession of Barnard's Pharmacy.

SHIPPED: Prior to 2–20–61, the ingredients were shipped from Ontario, Calif., Plymouth, Fla., and Chicago, Ill.

LABEL IN PART: (Btl.) "Ulcertrol A completely New Ulcer Treatment * * * Net Contents 12 Fl. Ozs. Ulcertrol, Inc. White Pigeon, Michigan. Ulcertrol is a new medication made by special processing and blending known only by Ulcertrol, Inc. – of the following: potatoe water, Orange, Lemon and Grapefruit Juices."

ACCOMPANYING LABELING: Circulars entitled "Ulcertrol The Completely New Ulcer Medication That is Guaranteed" and loose "*Ulcertrol*" bottle labels.

RESULTS OF INVESTIGATION: The dealer, Leroy F. Swinehart, t/a Ulcertrol, Inc., Red's Market, and Barnard's Pharmacy, manufactured, packed and labeled the article.

LIBELED: 4–11–61, W. Dist. Mich.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was an adequate and effective treatment for stomach ulcers.

DISPOSITION: 5–5–61. Default—destruction.

6689. S-M-C (Sulfur Mineral Concentrate) and Sulf-Hydro-Sol. (F.D.C. No. 45714. S. Nos. 53–561/2 R.)

QUANTITY: 15 1-pt. btls. of *S-M-C* and 144 2-oz. btls. of *Sulf-Hydro-Sol* at Minneapolis, Minn.

SHIPPED: 9–12–60, from Salt Lake City, Utah, by Colloidal Sulphur Co., Inc.

LABEL IN PART: (Btl.) "A Modern Spa In Your Home Bathe and Drink Your Way to Health and Beauty A Gift from the Gods S-M-C (Sulfur Mineral Concentrate) – Sulf-Hydro-Sol Colloidal Sulfur Products * * * The Colloidal Sulphur Company, Incorporated William A. Caudill, President, 599 Columbus Street Salt Lake City 16, Utah * * * Distributed by Organic Products, Inc. * * * Minneapolis 7, Minnesota * * * Rochester, Minnesota" and "Sulf-Hydro-Sol * * * active ingredients: Highly reactive sulfur complexes and Colloidal trace minerals, in a high potency concentrate supplying the univalent radical SH. Produced by The Colloidal Sulphur Co., Inc. * * * Salt Lake City, Utah. Distributed by Organic Products, Inc. * * * Always use S-M-C in conjunction with Sulf-Hydro-Sol for speedy and best results."

ACCOMPANYING LABELING: Leaflet entitled "A Modern Spa in Your Home."

LIBELED: 4–11–61, Dist. Minn.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the articles were an adequate and effective treatment for arthritis and certain metabolic diseases due to sulfur deficiency; that use of the articles would stimulate metabolism, revitalize and normalize body and cellular metabolism; and that one could bathe and drink his way to health and beauty by use of the articles.

DISPOSITION: 5–25–61. Default—destruction.

6690. Nevalite. (F.D.C. No. 45518. S. No. 42–776 R.)

QUANTITY: 8 16-oz. jars and 47 8-oz. jars of *Nevalite*, and 60 lbs. in bulk of powdered clay or clay-like material, at the Palisades Motel, Calistoga, Calif., in possession of Pharmaceuticals, a firm doing business at 2750 Hyde Street, San Francisco, Calif.

SHIPPED: In November and December 1960, from Sparks, Nev.

LABEL IN PART: (Jar) "Nevalite Contains Silicate * * * Aluminum * * * Iron * * * Calcium * * * Magnesium * * * Mix only what is required for each application and use immediately * * * Nevalite Inc., 1414 "B" St., Sparks, Nev."

ACCOMPANYING LABELING: A brochure entitled "The Palisades * * * Exclusive Representative for the New Nevalite Micropack Clay Treatment"; a single sheet headed "International Pharmaceuticals, Inc. * * * San Francisco 9, California Guarantee"; and a business card reading in part: "Newest and most effective method Physio-therapy yet discovered – Offers most lasting relief from symptomatic pains of arthritis, bursitis, rheumatism, gout, joint and muscular pain – Treatment without drugs – Widely tested – New Nevalite "MICROPACK" is 100% sanitary – Fresh clay for every treatment. Exclusively in Northern California at: The Palisades * * * 50 treatment rooms, clean, comfortable, private – Hot mineral water in every room."

RESULTS OF INVESTIGATION: The article in the jars was repacked from the above-mentioned raw material. The accompanying labeling of the article was printed in California on order of James E. Dwyer, the president of Pharmaceuticals.

LIBELED: 3–17–61, N. Dist. Calif.

CHARGE: 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for arthritis, rheumatism, neuralgia, myalgia, myositis, tendinitis, bursitis, chronic strain, burns, poison ivy dermatitis, coccygodynia, bruises, strains, and other conditions.

DISPOSITION: 5–29–61. Default—delivered to the Food and Drug Administration.

6691. Scandia Ovaline (cosmetic). (F.D.C. No. 45364. S. No. 64–544 R.)

QUANTITY: 65 2-oz. btls. and 26 4-oz. btls., individually cartoned, at San Francisco, Calif.

SHIPPED: 11–4–60, from New York, N.Y., by Scandia Sales Corp.

LABEL IN PART: (Btl.) "Scandia Ovaline * * * A unique Stimulant with a sting. * * * Leaves skin glowing and clear Scandia Sales Corp. New York."

ACCOMPANYING LABELING: Leaflets entitled "Scandia Secret Touch Cosmetics" and "Now You Can Get What Yoga Gives . . . Without Standing On Your Head"; and booklets entitled "Scandia Secret Touch Cosmetics."

LIBELED: 1–25–61, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective to nourish the skin, alter the body circulatory system, correct every complexion fault, treat a condition of "drying skin," banish over-oily residue from skin, cleanse clogged pores, revitalize lethargic tissues, and purify the skin; that it would cause the skin to be fed with new life from within, correct

all skin blemishes, and clear up disturbed skin; and 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient.

DISPOSITION: 5–15–61. Consent—claimed by Scandia Sales Corp., and released under bond for relabeling.

6692. Rel-Ong. (F.D.C. No. 45729. S. No. 72–573 R.)

QUANTITY: 780 ¼-oz btls. at Whittier, Calif.

SHIPPED: Between 12–6–60 and 3–1–61, from Trilby, Fla., by Meche Mfg. Co.

LABEL IN PART: (Btl.) "REL-ONG BY MECHE 1956 THE FINGERNAIL BEAUTIFIER Meche Mfg. Co., Trilby, Fla. * * * ½ Fl. Oz. * * * Rel-Ong is not a polish, not a plastic nail you brush on. * * * Active ingredients: Iodide Tinctures, Distillate of Hamamelidaceae, blended with essential oils and alcohol added as a preservative. Warning: * * * Antidote: * * * Directions:."

ACCOMPANYING LABELING: Display cards reading in part "Do Your Nails Break or Split? Are They Thin? Brittle? * * * Meche's Rel-Ong the Fingernail Beautifier"; folders entitled "Here They Are! Long Natural Glamor Nails – They Can Be Yours"; letters entitled "Rel-Ong What? – How? – Why?"; and Food and Drug Administration "Notice of Inspection" forms (FD Form 482) imprinted "Here's Positive Proof."

LIBELED: 4–24–61, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article would prevent and correct weak, thin, or brittle nails; aid nail growth; make nails grow longer, stronger, and thicker; prevent chipping, peeling, and breaking of nails; and that the article had the approval of the Food and Drug Administration.

DISPOSITION: 6–5–61. Default—destruction.

6693. Torulose tablets and powder, and JerOtene capsules. (F.D.C. No. 46053. S. Nos. 20–366/8 R.)

QUANTITY: 2 drums containing 59,000 tablets, 50 250-tablet btls., 14 500-tablet btls., and 1 1,000-tablet btl. of *Torulose tablets;* 46 1-lb. cans of *Torulose powder;* and 1 box containing 10,000 capsules of *JerOtene*, at Kalamazoo, Mich., in possession of Torrance Co.

SHIPPED: *Torulose tablets*, 7–3–61, from Chicago, Ill.; *Torulose powder*, 6–21–61, from Rhinelander, Wis.; and *JerOtene capsules*, 6–22–61, from South Whitley, Ind.

LABEL IN PART: (Drum) "Private Formula No. P–29.241 * * * Prepared for The Torrance Company. * * * Code #60824 F * * * Each tablet contains: Torula Yeast 7½ gr."; (btl.) "Torulose The King of Food Yeasts with the pleasing nut like flavor grown on the 'Sweet of the Spruce' Dosage: * * * Manufactured for Jerico Laboratories Kalamazoo, Michigan 8338"; (can) "Instant Yeast . . . With a Nut Like Flavor . . . Torulose * * * King of Food Yeasts * * * Manufactured for Jerico Laboratories, Kalamazoo, Michigan * * * Each Tablespoonful (8 grams) Contains: * * * Compared with a typical Brewer's Yeast * * * 60824"; (btl.) "JerOtene * * * Completely Organic 5000 U.S.P. Vitamin A Units of Carotene. 10 Intl. Units Vitamin E Dosage * * * Jerico Laboratories Kalamazoo, Michigan Designated for special dietary food purposes * * * Control No. 94173 Code No. 100."

ACCOMPANYING LABELING: Leaflets entitled "For Radiant Health Use Torulose" and "JerOtene Organic Carotene A Capsules"; also additional bottle labels for *Torulose tablets* and *JerOtene capsules.*

RESULTS OF INVESTIGATION: The *Torulose tablets and powder* in the bottles and cans were shipped in bulk and repacked and labeled by the dealer and, in the ordinary course of the dealer's business, the *JerOtene capsules* in the box were to be repacked into bottles labeled as described above.

LIBELED: 6–29–61, W. Dist. Mich.; amended libel filed 7–7–61.

CHARGE: *Torulose tablets and powder*, 502(a)—while held for sale, the labeling contained false and misleading representations that the articles were adequate and effective to promote radiant health and to promote the development of champions.

JerOtene capsules, 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective to promote growth, appetite and digestion; maintain a healthy appearance of hair and fingernails; maintain healthy balance of epithelial and nerve tissues; and to prevent infection of the respiratory system.

The libel alleged also that the *Torulose tablets and powder* and another article were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 7–11–61. Consent—claimed by the dealer and released under bond for relabeling.

6694. Sacro-Disc-30. (F.D.C. No. 44926. S. No. 4–563 R.)

QUANTITY: 346 100-tablet btls. at Baltimore, Md., in possession of Armisyl Products Co.

SHIPPED: 5–27–60, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "Sacro-Disc-30 Aneurine HC1 100 mg. U.S.P. Dose: 3 Tablets Daily * * * 12471 Distributed by Armisyl Products, 2806 W. Strathmore Ave. Baltimore 9, Md."

ACCOMPANYING LABELING: Brochures entitled "Suffering from Backache? Leg Pain?"

RESULTS OF INVESTIGATION: The article was repacked by the Barre Drug Co., Inc., Baltimore, Md., after shipment as described above. The bottles and labels for use in repacking the article were supplied by the Armisyl Products Co. The above-mentioned brochures were prepared locally for the Armisyl Products Co. Analysis showed that the article contained thiamine hydrochloride.

LIBELED: 10–3–60, Dist. Md.

CHARGE: 502(a)—while held for sale, the name "Sacro-Disc-30" and statements in the accompanying labeling of the article represented and suggested that the article was an adequate and effective treatment for backaches, leg pains, slipped disc, pains in general, arthritis, rheumatism, stiff joints, sleeplessness, nervous disorders, such as memory defects, depression, and severe agitation, and that the article was essential both to fertility and growth, and important to nerves, appetite, and digestion, which name and statements were false and misleading since the article was not an adequate and effective treatment for such conditions and purposes and was not capable of fulfilling the promises of benefit made for it; and 502(e)(2)—

the label of the article failed to bear the common or usual name of each active ingredient contained therein, namely, thiamine hydrochloride.

DISPOSITION: 8–2–61. Consent—destruction.

6695. **Propa-Vite capsules.** (F.D.C. No. 44365. S. No. 50–064 P.)

QUANTITY: 10 btls., each containing 1,000 capsules, at Evansville, Ind.

SHIPPED: 1–31–58, from Long Island City, N.Y., by Nysco Laboratories, Inc.

LABEL IN PART: (Btl.) "Propa-Vite Capsules Each capsule contains: Phenylpropanolamine hydrochloride 25 mgm. Methylcellulose 100 mgm. Vitamin A Acetate 1000 USP Units Vitamin D (Calciferol) 100 USP Units Thiamin Chloride 2 mgm. Riboflavin 1 mgm. Pyridoxine HCl 0.1 mgm. Niacinamide 10 mgm. Folic Acid 0.1 mgm. Vitamin B–12 (cobalamin conc.) 0.5 mcgm. Ascorbic Acid 10 mgm. Iron (from ferrous sulfate) 3 mgm. Calcium (from dicalcium phosphate) 50 mgm. Phosphorous (from dicalcium phosphate) 37.5 mgm. Iodine (from Potassium Iodide) 0.5 mgm. Fluorine (from calcium fluoride) 0.05 mgm. Copper (from copper sulfate) 1 mgm. Potassium (from potassium sulfate) 5 mgm. Manganese (from manganese sulfate) 1 mgm. Zinc (from zinc sulfate) 0.01 mgm. Magnesium (from magnesium sulfate) 1 mgm. Boron (from sodium borate) 0.05 mgm. * * * Nysco Laboratories, Inc. * * * Long Island City, N.Y."

LIBELED: On or about 3–21–60, S. Dist. Ind.

CHARGE: 502(a)—when shipped, the label statement "For use as an aid in reducing diets as an appetite depressant" was false and misleading since the article was not effective for this purpose.

DISPOSITION: 5–18–60. Default—destruction.

6696. **Leah's Delicious Diet with Ease.** (F.D.C. No. 45727. S. No. 50–287 R.)

QUANTITY: 206 btls., each containing 100 wafers, at Denver, Colo.

SHIPPED: 2–16–61, from New York, N.Y., by Approved Formulas, Inc.

LABEL IN PART: (Btl.) "Leah's Delicious Diet with Ease Food Supplement For Appetite Control The Natural Way Safe – Sane – Simple * * * Distributed by Leah's Foods, Aurora, Colo. No Drugs – No Tricks Really stems hunger like a meal – by providing nourishing protein. Only 4 calories per wafer. Children or Adults Chew or swallow 2 or 3 tasty wafers before meals or whenever hungry. Percent of Essential Amino Acids in each tablet: Arginine 3.34 * * * Each 16 grains contain: Protein 75% Fat 1.4% Carbohydrate 14% 11357."

LIBELED: 4–19–61, Dist. Colo.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was as adequate and effective to control appetite and to stem hunger as a meal would be.

The libel alleged also that the article was misbranded under the provisions of the Act relating to foods as reported in notices of judgment on foods.

DISPOSITION: 6–7–61. Default—destruction.

6697. **Oxy-Aid oxygen inhalator.** (F.D.C. No. 45720. S. No. 57–225 R.)

QUANTITY: 258 devices at New York, N.Y., in the possession of Oxy-Aid Scientific Corp.

SHIPPED: Between 2–1–58 and 3–31–58, from Chicago, Ill., by Emergency Medical Oxygen Co., Inc.

LABEL IN PART: (Device) "Oxy-Aid Emergency Oxygen U.S.P. * * * Directions * * * Contents 15 gallons of U.S.P. Oxygen compressed to 1800 lbs. per square inch at 70° F. * * * Refill when gauge reads 500 lbs. or less. * * * by Emergency Medical Oxygen Co., Chicago, Illinois."

ACCOMPANYING LABELING: Leaflets entitled "When Oxygen is needed . . . Oxy-aids," "Safety is a Stitch in Time," "Advertising: In France They Say," and "Dear Doctor"; and one window streamer entitled "When Breathing Fails."

RESULTS OF INVESTIGATION: The literature indicated that the article was a portable and cylinder-shaped device about 2" in diameter at the base, 12" long, designed to carry 15 gallons of compressed oxygen. It was equipped with an automatic pressure-reducing regulator, which reportedly allowed a measured flow of oxygen from the cylinder to a facial mask attachment.

Investigation revealed that the leaflets entitled "When Oxygen is needed . . . Oxy-Aid" and the window streamer were received with the shipments of the devices. The other leaflets were prepared by the dealer.

LIBELED: 4–20–61, S. Dist. N.Y.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was adequate and effective for overcoming heart failure, drowning, stroke, shock, and coma; for relieving asthma attacks, exhaustion, migraine headaches, and fatigue; and for combating oxygen deficiency due to hemorrhage, asphyxiation, drug poisoning, electric shock, fainting and hangover.

DISPOSITION: 5–15–61. Consent—claimed by Oxy-Aid Scientific Corp. The accompanying literature was destroyed and the devices were relabeled.

6698. Abunda Beauty device. (F.D.C. No. 44994. S. No. 23–198 R.)

QUANTITY: 159 individually ctnd. devices at Oklahoma City, Okla.

SHIPPED: 8–15–60, from Lubbock, Tex., by E. T. Abernathy.

LABEL IN PART: (Ctn.) "Abunda Beauty Abunda Products 20 Forty First Avenue, San Mateo, Calif."

ACCOMPANYING LABELING: Pamphlets entitled "Abunda Beauty – a lovelier you" and "Abunda Hydro Massage Bosom Beauty"; and leaflets entitled "Abunda Beauty, A New World of Loveliness," and "General Information."

RESULTS OF INVESTIGATION: Examination showed the article to be a plastic cup-shaped device with a water hose attachment. In use, the cup was intended to be placed over the female breast with the hose attachment connected to the household water service. The water was caused to be diffused or "swirled" in passing through a perforated disc in the cup base. The swirling water within the cup reportedly served to massage the bust.

LIBELED: 10–4–60, W. Dist. Okla.

CHARGE: 502(a)—when shipped, the name of the device "*Abunda Beauty*" and its labeling, contained false and misleading representations that the article was adequate and effective for reproportioning, firming, and uplifting the bosom; restoring, correcting, and arresting the aging processes affecting the bustline; restoring muscle and cell tissue; increasing circulation to lessen the chance of disease in breast tissues; eliminating waste material from the breast tissues and assisting the bust chemistry to function normally; and for providing an abundant bust through hydrotherapy.

DISPOSITION: 12–6–60. Default—delivered to Food and Drug Administration.

6699. Safe-T-Sun lamp. (F.D.C. No. 44665. S. No. 3–379 R.)

QUANTITY: 13 individually ctnd. lamps at York, Pa.

SHIPPED: 4–16–60, from Adwolfe (Marion), Va., by American Atlas Corp.

LABEL IN PART: (Floor stand) "Health Tan Lamp, American Atlas Corp. * * * Adwolfe Road, Va."; (filter) "Safe-T-Sun Lamp Filter * * * Manufactured by American Atlas, Marion, Va."; (envelope) "Health Tan Sun Lamp Filter * * * Sun Tan and Never Burn American Atlas Corporation, Marion, Virginia."

ACCOMPANYING LABELING: Booklet entitled "Summer Sun Rays When and Where You Want Them"; instruction sheet reading in part: "Instructions for Unpacking, Assembling, and Operating the Safe-T-Sun Lamp"; and pamphlet reading in part "Health Tan Lamp."

RESULTS OF INVESTIGATION: One sunlamp was assembled and the other 12 were unassembled. The assembled article consisted of an ultraviolet lamp fitted with a polyester film filter and adjustable reflector. The unit was then fitted to a floor stand.

LIBELED: 6–14–60, M. Dist. Pa.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for producing vitamin D to build strong bones and teeth; that the article would provide a healthful suntan, promote health of children, and provide the sunshine vitamins; and that the filter used with the lamp would allow the passage to the body of 90 percent of the light rays above 3100 angstroms to provide artificial sunlight.

DISPOSITION: 7–15–60 and 10–3–60. Default—3 devices delivered to Food and Drug Administration and remainder destroyed.

DRUG ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH PACKAGING REQUIREMENTS OF AN OFFICIAL COMPENDIUM

6700. Procaine penicillin G. (F.D.C. No. 45871. S. No. 73–767 R.)

QUANTITY: 12 boxes of 8 ctns. of 100 vials each, at Los Angeles, Calif.

SHIPPED: 4–26–61, from Philadelphia, Pa., by Philadelphia Laboratories, Inc.

LABEL IN PART: (Vial) "10 cc. Multiple Dose Vial * * * 3,000,000 Units Procaine Penicillin G Crystalline U.S.P. * * * Phila. Laboratories, Inc., Phila. 23, Pa."

LIBELED: 7–14–61, S. Dist. Calif.

CHARGE: 502(g)—when shipped, the article purported to be *procaine penicillin G*, a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and the article was not labeled as prescribed therein, since such compendium provides that *procaine penicillin G* conform to the regulations of the Federal Food and Drug Administration concerning certification of antibiotic drugs, whereas, the label of the article failed to bear lot numbers and expiration dates as required by regulations of the Federal Food and Drug Administration concerning certification of antibiotic drugs.

DISPOSITION: 8–23–61. Default—destruction.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U.S. GOVERNMENT PRINTING OFFICE: 1962

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6701–6740

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent; and (2) an injunction proceeding terminated upon the entry of a temporary injunction by consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the injunction proceeding was against the *firm* and *individual* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *August 30, 1962.*

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*For an imitation, and sale under name of, another drug, see No. 6712; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6707, 6722.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6701–6740

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its quality fell below the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions, or by children, where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

6701. Doxifer tablets and syrup. (F.D.C. No. 45806. S. Nos. 32–278/9 R.)

QUANTITY: 647 100-tablet btls. of *Doxifer Hematinico* and 215 8-oz. btls. of *Jarabe Doxifer-Hematinico*, at Santurce, P.R.

SHIPPED: 10–26–60 and 1–4–61, from Forest Hills, N.Y., by American Medicinal Corp.

LABEL IN PART: (Btl.) "Doxifer-Hematinico Formula – Cuatro Tabletas Contiene—Acido Folico 1.5 MG.—Dosis Sugerida: Adultos, 1 tableta cuatro veces al dia—American Medicinal Corporation, Forest Hills, New York – 49959" and (btl.) "Jarabe Doxifer-Hematinico De cuatro cucharaditas /20 cc./ Contiene – acido folico 1.5 mg.—Dosis sugerida: Adultos, 1 cucharadita cuatro veces al dia – American Medicinal Corporation Forest Hills, New York – 01049."

LIBELED: 5–18–61, Dist. P.R.

CHARGE: 502(j)—when shipped, the articles were dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling, since the articles under the directions for use, would supply 1.5 mg. of folic acid daily.

DISPOSITION: 8–8–61. Consent—destruction.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUG FOR HUMAN USE

6702. Hope's Worm Rid. (F.D.C. No. 43535. S. No. 56–372 P.)

QUANTITY: 140 btls. at Charleston, S.C.

SHIPPED: 7–27–59, from Clayton, Mo., by Hope Co.

LABEL IN PART: "Hope's Worm-Rid For Pin and Roundworms * * * Each teaspoonful (5 cc.) contains: Piperazine Citrate Equivalent to 500 mg. Piperazine Hexahydrate * * * Directions: * * * Adults and children * * * The Hope Co., Clayton 5, Mo."

LIBELED: 9–19–59, E. Dist. S.C.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: 11–8–61. Consent—destruction.

DRUG FOR VETERINARY USE

6703. Felco Feed Premix. (F.D.C. No. 45147. S. No. 27–424 R.)

QUANTITY: 118 bales, 6 10-lb. bags each, at Fort Dodge, Iowa.

SHIPPED: 7–7–60, from Kansas City, Mo., by Farmers Elevator Service Co., Inc.

LABEL IN PART: (Bag) "Felco Feed Premix medicated for the prevention of Coccidiosis in Chickens * * * Active drug ingredients: Bithionol 10.0 percent Methitriazamine 2.0 percent * * * Manufactured for Farmers Elevator Service Company * * * Fort Dodge, Iowa."

LIBELED: 11–18–60, N. Dist. Iowa; amended libel 1–29–62.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: Claimant, Farmers Elevator Service Co., Inc., filed an answer denying the charge and alleging that said article could be legally introduced or delivered for introduction into interstate commerce, by reason of the fact that a new drug application was effective at the time of its shipment in interstate commerce; that the said article did not contain changes that were significant from the standpoint of safety of the drug and that a supplemental new drug application was not therefore required as to said article; that said article was not a new drug and thus no new drug application was necessary for said article; and that claimant had an effective application for an exemption from certification of a feed containing an antibiotic pursuant to Section 507, a necessary component of which exempted final product was said article, so that a new drug application was not required for said article in view of the provision of Section 507(e) stating that any drug subject to Section 507 shall not be subject to Section 505.

Thereafter, by permission of the court, the claimant withdrew its claim and answer without admitting the allegations of the libel, stating that no useful purpose would be served by contesting the action since a supplemental new drug application was then effective with respect to the article and that accordingly the determination of the issues involved was moot insofar as future interstate shipments of the article were concerned, and since the value of the libeled article was much less than would be the cost of defending the action. Judgment of condemnation was thereupon entered on 1–29–62, and the court ordered that the article be destroyed.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6704. Vitamin tablets and vitamin-and-mineral tablets. (F.D.C. Nos. 46275, 46278. S. Nos. 78–747/8 R.)

QUANTITY: 94 btls., each containing 50 or 100 *vitamin-and-mineral tablets*, at Mission, Tex.; and 42 btls., each containing 50 or 100 *vitamin tablets*, at Donna, Tex.

SHIPPED: On unknown dates, from Chicago, Ill.

LABEL IN PART: (Btl.) "Olavite-M Therapeutic Vitamin & Mineral Tablets * * * Olafsen Vitamins, Inc., Dist. Chicago, Illinois. Each tablet contains * * * Folic Acid 0.5 mg. * * * Dosage: 1 or 2 tablets daily," and "Olavite Therapeutic Vitamin Tablets * * * Olafsen Vitamins, Inc., Dist., Chicago, Illinois. Each tablet contains * * * Folic Acid 0.5 mg. * * * Dosage: 1 or 2 tablets daily."

LIBELED: 8–24–61, S. Dist. Tex.

CHARGE: 503(b)(4)—while held for sale, the labels of the articles failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10–9–61. Default—destruction.

6705. Viril-Lam tablets. (F.D.C. No. 45947. S. No. 32–285 R.)

QUANTITY: 389 25-tablet btls. at Santurce, P.R.

SHIPPED: 3–31–61, from Oceanside, N.Y., by Lambda Pharmacal Laboratories.

LABEL IN PART: "Lambda Viril-Lam Each tablet supplies: Methyl testosterone 10 mg. Pituitary extract (anterior lobe) 4 mg. Adrenals 4 mg. Yohimbine hydrochloride 5 mg. Vit. A (from Fish liver oil) 5,000 U.S.P. Units Vitamin E 1 mg. Vitamin B_1 5 mg. Zinc Phosphide 1.5 mg. Strychnine sulfate 0.05 mg. Dosage: * * * Lambda Pharmacal Laboratories, Inc., 391 Atlantic Ave., Oceanside, N.Y."

LIBELED: 6–20–61, Dist. P.R.

CHARGE: 503(b)(4)—when shipped, the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 8–10–61. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

6706. Candy-coated chewing gum. (F.D.C. No. 46440. S. No. 84–605 R.)

QUANTITY: 7 ctns., containing a total of 6,000 units, at New York, N.Y., in possession of Kean Energizing Health Products, Inc.

SHIPPED: 5–1–61, from Newark, N.J.

LABEL IN PART: (Plastic box) "15 One For The Road 15 Natural Coffee Base 'Drive-Safers' Pep-Ups Kean Brand Chicles Vitamin A Fortified Caffeine Activated Safe-Pleasant as Coffee * * * An Adult Product," "2 Pep-Ups* Chicles Provide the Energy & Stimulation of One Full Cup of Coffee, Chew As Many As Desired," and "Each Chicle Contains 5000 Units Vitamin A To Aid Eyesight Fatigue Resist Headlight Glare."

ACCOMPANYING LABELING: A package insert reading in part "Real Coffee Base plus Vitamin A and Caffeine"; a folder reading in part "New! Chew A Full Cup of Zesty Coffee Kean's Pep-Ups Brand"; a window streamer reading in

part "Here NOW! Real Coffee Base Caffeine Activated Vitamin 'A' Fortified Kean's Pep-Ups Brand Chicles, Only Chewing Gum of its Kind in the World"; form letter headed "Kean Energizing Health Products"; and display box inserts reading in part "New! * * * Pep-Ups* Awakeners— 'Drive Safers' Alerters."

RESULTS OF INVESTIGATION: The article was in bulk form and was, in the normal course of the dealer's business operations, to be repacked into clear plastic 15-unit rectangular boxes containing insert labels.

The label on the bulk material stated that the article contained "½ gr. anhydrous Caffeine per tablet" which was about ⅕ of the caffeine content of a cup of coffee.

LIBELED: 9–18–61, S. Dist, N.Y.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was capable of making one energetic; awakening, and promoting alertness and safer driving; aiding or resisting "eyesight fatigue" resulting from exposure to sun, daylight, headlight glare, and artificial lighting; having a sobering and counteractive effect in mild hangover condition; overcoming car sickness; and that the article was the only chewing gum of its kind in the world; that it contained a significant amount of caffeine which was "activated," "activating," and "fortified"; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the conditions and purposes for which it was offered.

DISPOSITION: 11–8–61. Consent—claimed by the dealer and destroyed.

6707. Various prescription drugs. (F.D.C. No. 46438. S. Nos. 3–181/8 T.)

QUANTITY: Various quantities, having an approximate total value of $1,000, at Baltimore, Md., in possession of Golditch Pharmacy.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample Not To Be Sold," "Physician Sample," "Complimentary Package," "Sample Not For Sale," and "Physician Sample Not To Be Sold," or similar wording.

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs which had been repacked by the dealer from physicians' samples into bottles to which had been affixed labels bearing the brand names of the drugs, the words "Professional Sample Not To Be Sold," "Complimentary Package," "Sample Not For Sale," or similar wording, and the names and addresses of the manufacturers, packers, or distributors located outside the State of Maryland.

Some of the articles were prescription drugs originally intended for use as samples for physicians and others lawfully engaged in dispensing prescription drugs, which had not, at the time the articles were libeled, been repacked by the dealer and which bore labels similar to the above articles.

Some of the articles were prescription drugs repacked as above from physicians' samples into bottles bearing labels which contained the words "Physician Sample" or similar wording and such brand names for the drugs as are indicative of their manufacture outside the State of Maryland, but did not bear the names and addresses of the manufacturers, packers, or distributors located outside the State of Maryland.

Some of the articles were prescription drugs which had been repacked by the dealer into bottles to which had been affixed labels bearing such brand names for the drugs as were indicative of their manufacture outside the State of Maryland, but which did not contain the names and addresses of the manu-

facturers, packers, or distributors, and original identifying lot or control numbers.

LIBELED: 9–5–61, Dist. Md.

CHARGE: 502(a)—while held for sale, the words "Professional Sample Not To Be Sold," "Physician Sample," "Complimentary Package," "Sample Not For Sale," "Physician Sample Not To Be Sold," and similar wording on the labels of a number of the articles, were false and misleading as applied to the articles then in possession of a repacker and intended for sale, and not then intended for use as "complimentary–not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(1)—a number of the articles failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and 502(f)(1)—the labels of a number of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were drugs subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the packages of the drugs as required by regulations.

DISPOSITION: 10–3–61. Default—destruction.

6708. Neo-Cough cough syrup. (F.D.C. No. 45954. S. No. 79–514 R.)

QUANTITY: 37 cases, each containing 36 3-oz. btls., at Arlington, Va.

SHIPPED: 10–27–59 and 1–3–61, from Philadelphia, Pa., by Hance Bros. & White.

LABEL IN PART: (Btl.) "Neo-Cough Cough Syrup For Children * * * Distributors Arlco Drug Co. * * * Each Fluid ounce Contains: * * * d-Methorphan H. Br. 15 mg. * * * Phenylephrine HCl. 15 mg. * * * Directions: Infants, from 3 months to 1 year, 10 to 15 drops."

LIBELED: 6–19–61, E. Dist. Va.

CHARGE: 502(f)(2)—when shipped, the labeling failed to bear adequate warnings against its use by individuals with high blood pressure, heart disease, diabetes, or thyroid disease; to keep it out of the reach of children; against its administration to children under 2 years of age; against its use by persons with a high fever or persistent cough; and that a persistent cough may indicate the presence of a serious condition.

The libel alleged also that other articles were adulterated under the provisions of the Act relating to foods, as reported in notices of judgment on foods.

DISPOSITION: 7–6–61. Consent—claimed by Arlco Drug Co., Arlington, Va., and relabeled.

6709. Adolphus Massagerizer and Wahl Powersage Electric Vibrator. (F.D.C. No. 46078. S. Nos. 84–595/6 R.)

QUANTITY: 11 Massagerizer devices and 11 vibrator devices at New York, N.Y., in possession of Adolphus Hohensee.

SHIPPED: Prior to 6–28–61, from outside the State of New York.

RESULTS OF INVESTIGATION: Examination showed that the Massagerizer was a vibrating pillow-like box having 2 metal ends, the other 4 sides being padded and covered with a pink rubberized material; and that one end had an adjustable knob-switch to turn the device on and adjust its speed of vibration.

Examination showed that the Powersage Vibrator was an electric hand massager, having 2 elastic metal bands that attached the device to the back of the hand thus leaving the palm free to massage where desired.

LIBELED: 7–13–61, S. Dist. N.Y.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use as a treatment for and preventive of migraine headache, impaired hearing, prostate gland trouble, internal cancer, tumors, receding gums, poor vision, poor digestion, varicose veins, and hardening of the arteries; and to clear sinuses; remove wrinkles; rejuvenate personality glands; remove cobwebs from the brain; and for spot reducing, which were the diseases, conditions, and purposes for which the articles were recommended in oral statements made by Adolphus Hohensee during the course of 3 lectures given at New York, N.Y., on or about June 28 and 29, 1961.

DISPOSITION: 8–22–61. Default—delivered to the Food and Drug Administration.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS FOR HUMAN USE

6710. Sal-Amino C tablets. (F.D.C. No. 45745. S. No. 62–717 R.)

QUANTITY: 95 100-tablet btls. and 149 1,000-tablet btls. at Columbus, Ohio, in possession of Columbus Hospital Supply Co.

SHIPPED: In March or April 1953, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "List No. 2083 Sal-Amino C Tablets Control No. 9431 Distributed by Columbus Hospital Supply Company Columbus 15, Ohio Caution: * * * Each tablet Represents: Sodium Salicylate (3 gr.) 200.0 mg. Calcium Succinate (2 gr.) 133.3 mg. Para Aminobenzoic Acid (1 gr.) 66.7 mg. Vitamin C (0.3 gr.) 20.0 mg."

RESULTS OF INVESTIGATION: Examination showed that the article contained 47 percent of the declared amount of ascorbic acid (vitamin C) and 75 percent of the declared amount of para-aminobenzoic acid.

LIBELED: 4–26–61, S. Dist. Ohio.

CHARGE: 501(c)—while held for sale, the strength of the article differed from and its quality fell below that which it purported or was represented to possess; and 502(a)—the label statements "Each Tablet Represents: * * * Para Aminobenzoic Acid (1 gr.) 66.7 mg. Vitamin C (0.3 gr.) 20.0 mg." were false and misleading as applied to an article that contained less than the declared amounts of these ingredients.

DISPOSITION: 6–16–61. Default—destruction.

6711. Secobarbital sodium capsules. (F.D.C. No. 46140. S. No. 97–334 R.)

QUANTITY: 1 100-capsule btl., 12 500-capsule btls., and 45 1,000-capsule btls., at Buffalo, N.Y.

SHIPPED: From Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: (Btl.) "No. 4090 * * * Secobarbital Sodium * * * 1½ Grain * * * Distributed by Direct Laboratories, Inc., Buffalo 4, New York, Control 9228."

RESULTS OF INVESTIGATION: The article was repacked and labeled by the dealer after its shipment in bulk as described above. Analysis showed that the article failed to meet the United States Pharmacopeia requirement for *secobarbital sodium capsules* in that its weight variation was not in accordance with the Pharmacopeia.

LIBELED: 7–27–61, W. Dist. N.Y.

CHARGE: 501(b)—when shipped and while held for sale, the article purported to be and was represented as *secobarbital sodium capsules*, a drug which is recognized in the United States Pharmacopeia, an official compendium, and its quality differed from the standard set forth in such compendium; and 502(a)—the label statement "*Secobarbital Sodium Capsules*" was false and misleading as applied to an article which failed to meet the requirements of the United States Pharmacopeia for such drug.

DISPOSITION: 8–31–61. Default—destruction.

6712. Reserpine tablets. (F.D.C. No. 45812. S. No. 66–906 R.)

QUANTITY: 900 tablets at Oklahoma City, Okla.

SHIPPED: Prior to 4–26–61, by an unknown shipper, from outside the State of Oklahoma.

LIBELED: 5–25–61, W. Dist. Okla.

CHARGE: 501(d)(2)—while held for sale, an imitation drug had been substituted for an authentic drug; 502(a)—the label statements "Serpasil" and "Ciba" were false and misleading as applied to a product which was an imitation of Serpasil; 502(i)(2)—the article was an imitation of another drug; 502(i)(3)—the article was offered for sale under the name of another drug namely, Serpasil.

DISPOSITION: 6–19–61. Default—destruction.

6713. Vitamin B complex with vitamin B_{12} injection. (F.D.C. No. 46467. S. No. 79–855 R.)

QUANTITY: 42 individually cartoned 30-cc. vials at Baltimore, Md.

SHIPPED: 1–30–61, from New Rochelle, N.Y.

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 22 percent of the declared amount of vitamin B_{12}.

LIBELED: 9–22–61, Dist. Md.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Each cc. contains: Vitamin B_{12} 30 mg." was false and misleading as applied to an article which contained less than the declared amount of vitamin B_{12}.

DISPOSITION: 10–25–61. Default—destruction.

6714. Rubber prophylactics. (F.D.C. No. 45792. S. No. 80–921 R.)

QUANTITY: 38 ctns., each containing 48 3-unit boxes, at Natchitoches, La.

SHIPPED: 3–15–61, from Kansas City, Mo., by M & M Rubber Manufacturing Co.

LABEL IN PART: (Ctn.) "One Gross Viking Super Thin Transparent Prophylactics Threes."

RESULTS OF INVESTIGATION: Examination showed that 2.8 percent of the units examined were defective in that they contained holes.

LIBELED: 5–11–61, W. Dist. La.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "Sold for Prevention of Disease" was false and misleading as applied to an article containing holes.

DISPOSITION: 6–27–61. Default—destruction.

6715. Rubber prophylactics. (Inj. No. 407.)

COMPLAINT FOR INJUNCTION FILED: 7–3–61, W. Dist. Mo., against M & M Rubber Co., Inc., and Neil F. Murry, Jr., Kansas City, Mo.

CHARGE: The complaint alleged that the defendants were engaged in the business of receiving bulk shipments of rubber prophylactics, made in Puerto Rico and Japan, and thereafter testing, packaging, labeling, selling and distributing the articles in interstate commerce; and that when introduced into interstate commerce, by the defendants, the articles were adulterated under 501(c) in that their quality fell below that which they purported and were represented to possess in that they contained holes, and were misbranded under 502(a) in that the labeling contained false and misleading representations that the articles were effective in the prevention of disease.

It was alleged further that the adulterated and misbranded condition of the articles resulted from, among other things, the defendants' failure to test all lots of the articles for the presence of holes; the use of insufficient electric current and insufficient electrolyte solution in the operation of the electronic testing machine used for the detection of holes in the articles; dumping cap-type rubber prophylactics, after testing, into a squirrel cage-type tumbler with hardwood sawdust for drying purposes; the dumping of the cap-type prophylactics and sawdust, after drying, into another tumbler made of hardware cloth and the operation of such tumbler until the sawdust had been removed; the rolling of regular length prophylactics while partly wet, and the presence of untested prophylactics in the room used for the packaging of the tested prophylactics.

The complaint alleged also that the defendants had been warned of the conditions by several inspections and by numerous seizures of defective prophylactics.

DISPOSITION: On 7–3–61, the court entered a temporary restraining order, without notice, restraining the defendants from the acts complained of.

On 9–15–61, the defendants having consented, the court entered a temporary injunction enjoining the defendants from introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce any prophylactics which are (a) adulterated in that they contain holes, and (b) misbranded in that their labeling contains false and misleading representations that the articles are effective in the prevention of disease.

The defendants were enjoined further from introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, prophylactics, unless or until:

(a) Procedures are established which will assure that each prophylactic received by the defendants is adequately tested to determine the presence of holes therein.

(b) Written instructions for the proper operation of the electronic machine used in testing the prophylactics for the presence of holes are posted on, or adjacent to, such machine.

(c) Tests for the presence of holes in the prophylactics are conducted by competent trained employees under the supervision of a designated supervisory employee.

(d) The electronic testing machine is operated with sufficient electric current and sufficient electrolyte solution, and in an otherwise proper manner so as to assure the detection of holes in the prophylactics.

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(e) The tested prophylactics are dried in a manner which will remove all moisture and will not cause holes in the prophylactics.

(f) Any untested prophylactics now being held in the packing room of defendants' plant are removed to a different room for storage until tested.

(g) Procedures are established which will assure that no untested prophylactics are placed in the packing room prior to being tested for the presence of holes; and,

(h) All prophylactics which have been the subject of prior detention under the provisions of Chapter 801 of the Act [21 U.S.C. 381], and which purport to have been subsequently tested and packaged under the supervision of representatives of the Food and Drug Administration and released from import detention by the Food and Drug Administration, have been resampled by the Food and Drug Administration for the purpose of determining that the said released lots are free from holes and can be accurately identified with specific lots previously tested by the Food and Drug Administration under the provisions of 21 U.S.C. 381; and any such lots so resampled and retested shall not be introduced or delivered for introduction, or caused to be introduced or delivered for introduction into interstate commerce, if upon the above described retesting they fail to comply with the Act, unless and until such defective lots shall have been processed in the manner set forth in paragraph (i) hereinafter; and all costs of resampling and testing as hereinbefore set forth, shall be borne by the defendants.

(i) All prophylactics which purport to have been tested for the presence of holes, except such detained lots as are hereinbefore described in paragraph (h), and which are now held in defendants' plant in packaged or unpackaged form are retested for the presence of holes, and the retested prophylactics which contain no holes are dried in a manner which will remove all moisture and will not cause holes in the prophylactics, and the retested prophylactics which contain holes are destroyed, with such retesting, drying, and destruction being done under the supervision of an authorized representative of the Food and Drug Administration, Department of Health, Education, and Welfare, and all costs of said supervision being borne by the defendants; and,

(j) All stocks which are to be tested and/or retested as hereinbefore set forth in paragraphs (h) and (i) shall be retained intact in the defendants' plant until a release in writing has been furnished covering said lots by the Food and Drug Administration; such releases to be furnished promptly upon completion of such examinations as may be required.

The decree of temporary injunction provided also that it may be dismissed upon motion of the defendants, jointly and seasonably made, upon a satisfactory showing that the stocks of imported prophylactics now held in the firm's plant, or elsewhere under its control, have been satisfactorily brought into compliance with the Federal Food, Drug, and Cosmetic Act and the terms of this Order and a release in writing furnished by the Kansas City District of the Food and Drug Administration as hereinbefore set forth, and upon further showing that the firm has conducted its operations in compliance with the Act and the terms of this Order for a period of seven months following the release in writing of all stocks of imported prophylactics now held in defendants' plant or elsewhere under the control of the defendants.

DRUG FOR VETERINARY USE

6716. Medicated feed. (F.D.C. No. 45260. S. Nos. 22-364 R, 22-369 R.)

QUANTITY: 132 bags of *Professional Chick Spicer Atoms* and 68 bags of *Professional Broiler Atoms* at Omaha, Nebr.

SHIPPED: On 4–22–60 and 5–24–60 (Chick Spicer Atoms), and 6–7–60 and 7–1–60 (Broiler Atoms), from Kansas City, Mo., by Staley Milling Co. (Spencer Kellogg & Sons, Inc.).

LABEL IN PART: (Bag) "Professional Chick Spicer Atoms * * * Spencer Kellogg and Sons, Inc. Professional Feeds Division, Kansas City & St. Louis 25 Lbs. Net * * * Active Drug Ingredients: Furazolidone (nf–180) 0.011% (100 grams per ton) Chlortetracycline (aureomycin) 0.05 grams per lb. (100 grams per ton)"; "Professional Broiler Atoms * * * 50 Lbs. Net Staley Milling Company, Kansas City & St. Louis"; and (tag) "50 Lbs. Net Broiler Grower Atoms Medicated * * * Ingredients: * * * 3 Nitro 4-Hydroxyphenylarsonic Acid 0.005%; Nicarbazin 0.0125%."

LIBELED: 12–9–60, Dist. Nebr.

CHARGE: 501(c)—when shipped and while held for sale, the strength of the articles differed from, and their quality fell below, that which they purported and were represented to possess since the Chick Spicer Atoms contained approximately 40 percent of the labeled amount of furazolidone, and the Broiler Atoms contained approximately 72 percent of the labeled amount of 3-nitro,-4-hydroxyphenylarsonic acid.

DISPOSITION: 9–5–61. Consent—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

6717. Various prescription drugs. (F.D.C. No. 46252. S. Nos. 76–150 R, 76–152/4 R, 76–156 R, 76–163/5 R.)

QUANTITY: 3,565 tablets and capsules, and 41 btls. of liquid preparations, at Jacksonville, Fla., in possession of Johnston's Pharmacy.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Patient Starter Package," "Professional Trial Package," "Professional Sample Not for Sale," "Sample Not To Be Sold," "Physician's Professional Package," "Special Package for the Medical Profession Only," "Physician's Test Package," or similar wording.

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs, originally intended for use as samples for physicians and others lawfully engaged in dispensing prescription drugs, bearing labels containing a "complimentary – not to be sold" professional sample legend, and containing also the names and addresses of manufacturers, packers, or distributors located outside the State of Florida.

Some of the articles were prescription drugs originally intended for investigational use and bearing labels containing the words "Caution: New Drug Limited by United States Law to Investigational Use," or similar wording, and the names and addresses of manufacturers, packers, or distributors located outside the State of Florida.

LIBELED: 8–15–61, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the words "Patient Starter Package," "Professional Trial Package," "Professional Sample Not for Sale," "Sample Not To Be Sold," "Physician's Professional Package," "Special Package for the Medical Profession Only," "Physician's Test Package," and similar wording on

*See also Nos. 6706, 6707, 6710–6715.

the labels of a number of the articles, were false and misleading as applied to the articles then in the possession of a repacker and intended for sale, and not then intended for use as "complimentary – not to be sold" samples for physicians and others lawfully engaged in dispensing prescription drugs; and 502(a)—the words "Caution: New Drug Limited by United States Law to Investigational Use," and similar wording on the labels of a number of the articles, were false and misleading as applied to the articles then in the possession of a repacker and intended for sale, and not then intended for investigational use.

DISPOSITION: 10–3–61. Default—destruction.

6718. Various prescription drugs. (F.D.C. No. 46271. S. Nos. 99–101 R, 99–103/4 R, 99–106/7 R, 99–111 R.)

QUANTITY: Various quantities having an approximate total value of $400, at Rochester, N.Y., in possession of Monroe Pharmacy.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Physician's Sample – Not To Be Sold," "Physician's Professional Package," "Complimentary," "Physician's Sample," "Sample: Not To Be Sold," or similar wording, and (some labels) "Caution: New Drug – Limited By Federal Law to Investigational Use," or similar wording.

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs, originally intended for use as samples for physicians and others lawfully engaged in dispensing prescription drugs, and bearing the prescription legend, a "complimentary – not to be sold" professional sample legend, and the names and addresses of the manufacturers, packers, or distributors located outside the State of New York.

Some of the articles were prescription drugs originally intended for investigational use and bearing labels containing the words "Caution: New Drug – Limited By Federal Law To Investigational Use," or similar wording, and the names and addresses of manufacturers, packers, or distributors located outside the State of New York.

LIBELED: 8–22–61, W. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the words "Physician's Sample – Not To Be Sold," "Physician's Professional Package," "Complimentary," "Physician's Sample," "Sample: Not To Be Sold," or similar wording on the labels of a number of articles, were false and misleading as applied to the articles then in the possession of a repacker and intended for sale, and not then intended for use as "complimentary – not to be sold" samples for physicians and others lawfully engaged in dispensing prescription drugs; and 502(a)—the words "Caution: New Drug – Limited By Federal Law To Investigational Use," and similar wording on the labels of a number of articles, were false and misleading as applied to the articles then in the possession of a repacker and intended for sale, and not then intended for investigational use.

DISPOSITION: 10–13–61. Default—destruction.

6719. Various prescription drugs. (F.D.C. No. 46193. S. Nos. 62–071/6 R.)

QUANTITY: 121,920 tablets, 73 envelopes containing additional tablets, and 200 btls. of liquid, at Overland Park, Kans., in possession of William H. Carlos.

SHIPPED: On unknown dates, from outside the State of Kansas.

LABEL IN PART: "Professional Sample" or "Complimentary."

RESULTS OF INVESTIGATION: The articles were originally intended as physician's samples and were obtained by the holder during the time that he was a drug salesman.

LIBELED: 8–1–61, Dist. Kans.

CHARGE: 502(a)—while held for sale, the words "Professional Sample" and "Complimentary" on the labels were false and misleading as applied to the articles which were intended for sale, and not then intended for use as "complimentary – not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs.

DISPOSITION: 9–29–61. Default—destruction.

6720. **Various prescription drugs.** (F.D.C. No. 46076. S. Nos. 69–361/73 R.)

QUANTITY: 6 ctns., having an approximate total value of $5,000, at Chicago, Ill., in possession of Ballin Drugs, Inc.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Sample Not To Be Sold," "Professional Sample," "Physicians Professional Package," or similar wording.

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs which had been repacked by the dealer, Ballin Drugs, Inc., from physicians' samples into containers to which had been affixed labels bearing a "complimentary – not to be sold" professional sample legend, and the names of manufacturers, packers, or distributors located outside the State of Illinois.

Some of the articles were prescription drugs which had not, at the time the libel was filed, been repacked by the dealer and originally were intended for use as samples for physicians and others lawfully engaged in dispensing prescription drugs and which bore labels containing "complimentary – not to be sold" professional sample legend, and the names of manufacturers, packers, or distributors located outside the State of Illinois.

LIBELED: 7–13–61, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the statements "Sample Not To Be Sold," "Professional Sample," "Physicians Professional Package," "Physician Sample," and similar wording borne on the labels of said articles, were false and misleading as applied to the articles then in possession of a repacker and intended for sale, and not then intended for use as "complimentary – not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs.

DISPOSITION: 9–1–61. Default—destruction.

6721. **Various prescription drugs.** (F.D.C. No. 46038. S. Nos. 84–444/55 R.)

QUANTITY: 62 ctns., having an approximate total value of $7,000, at Newark, N.J., in possession of Joseph Iannarone, t/a Armory Drug Store.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: "Professional Sample," "Complimentary Package," "Sample: Not To Be Sold," "Physicians trial package," "Professional Sample: Not to be Sold," "For Clinical Use," and "Complimentary," or similar wording.

RESULTS OF INVESTIGATION: The articles were prescription drugs originally intended for use as samples for physicians and others lawfully engaged in distributing prescription drugs, and bearing labels containing a "complimentary – not to be sold" professional sample legend, and containing also the names and address of manufacturers, packers, or distributors located outside the State of New Jersey.

LIBELED: 6–23–61, Dist. N.J.

CHARGE: 502(a)—while held for sale, the statements "Professional Sample," "Complimentary Package," "Sample: Not to be sold," "Physicians trial package," "Professional Sample: Not to be Sold," "For Clinical Use," and "Complimentary," and similar wording borne on the labels of the articles were false and misleading as applied to the articles then in possession of a repacker and intended for sale, and not then intended for use as "complimentary – not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs.

DISPOSITION: 8–23–61. Default—destruction.

6722. Various prescription drugs. (F.D.C. No. 45961. S. Nos. 69–463/78 R, 69–480/87 R.)

QUANTITY: Unknown quantities at Schiller Park, Ill., in possession of Nathan H. Baier.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Physician's Sample," "Professional Sample," "Clinical Trial Supply," "Physician Sample for Clinical Use," "Sample Not To Be Sold," "Complimentary," "Physicians Professional Package," or "Sample."

RESULTS OF INVESTIGATION: The articles consisted of prescription drugs repacked from physicians' samples into containers having labels bearing brand names indicative of manufacture outside the State of Illinois and quantities of prescription drugs which were not yet repacked, originally intended for use as samples, and still in original sample packages bearing the names and addresses of manufacturers, packers, or distributors outside the State of Illinois.

LIBELED: 6–15–61, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the statements "Physician's Sample," "Clinical Trial Supply," "Physician Sample for Clinical Use," "Sample Not To Be Sold," "Complimentary," "Physician's Professional Package," "Sample," and similar wording on the labels of the articles of drug were false and misleading as applied to articles then in possession of a repacker and intended for sale, and not then intended for use as "complimentary—not for sale," samples for physicians and others lawfully engaged in dispensing prescription drugs; and 502(b)(1)—the repacked articles of drug failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: 8–4–61. Default—destruction.

6723. Prescription X–259 powder. (F.D.C. No. 45784. S. No. 47–375 R.)

QUANTITY: 47 65-gram btls. at Taylor, Mich.

SHIPPED: 2–25–61, from Youngstown, Ohio, by R. P. White Drug Co.

LABEL IN PART: "Prescription X–259 * * * 65 Grams R. P. White Drug Co., Youngstown, Ohio Caution: * * * Directions: * * * Active Ingredients: Bismuth Subsalicylate, Magnesium Oxide, Magnesium Carbonate, Magnesium Trisilicate, Sodium Bicarbonate, Oil of Fennel, Powdered Extract of Belladonna Leaves, 6 Mgm. to Gm."

ACCOMPANYING LABELING: A display placard reading in part "Effective Long-Lasting Relief For Stomach and Duodenal Ulcers."

RESULTS OF INVESTIGATION: The shipper had shipped the display placard with the article and the dealer had used the display placard in conjunction with a display of the article.

LIBELED: 5–8–61, E. Dist. Mich.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for stomach and duodenal ulcers.

DISPOSITION: 8–30–61. Default—destruction.

6724. Robinson Stomach Tablets with Adiphenine. (F.D.C. No. 45920. S. No. 67–767 R.)

QUANTITY: 40,000 tablets in 100 100-tablet btls., 198 50-tablet btls., 100 25-tablet btls., and 2 drums, at Seagoville, Tex.

SHIPPED: 8–25–61, from Long Island City, N.Y., by Nysco Laboratories, Inc.

LABEL IN PART: (Btl. and drum) "Robinson Stomach Tablets with Adiphenine * * * Manufactured for Old Texas Pharmaceutical Co., * * * Seagoville, Texas Each Tablet Contains Aluminum-magnesium-hydroxy-carbonate 10 grains Adiphenine hydrochloride 5 mgm. * * * Average Dose—1–2 tablets between meals. For use in the treatment of gastric hyperacidity and in the management of ulcer" and (drum only) "Nysco Laboratories, Inc., Long Island City, N.Y."

RESULTS OF INVESTIGATION: The dealer had repacked the article into bottles from the bulk drums.

LIBELED: 6–19–61, N. Dist. Tex.

CHARGE: 502(a)—when shipped, the label of the article contained false and misleading representations that the article was an adequate and effective treatment for gastric ulcers.

DISPOSITION: 8–21–61. Default—destruction.

6725. Neutsu herb (Ledum latifolium). (F.D.C. No. 46035. S. No. 49–790 R.)

QUANTITY: 1,000 lbs. in various bags and bbls., at Salmon, Idaho, in possession of Fred J. Brough, t/a Neutsu Herb.

SHIPPED: Some time in 1935, from the State of Montana.

ACCOMPANYING LABELING: Leaflet entitled "Neutsu (Ledum LATIFOLUM)"; and postcard order blank addressed "Neutsu c/o F. Brough, Box 126, Salmon, Idaho."

RESULTS OF INVESTIGATION: Examination showed the article to be a cut-up plant material consisting of stems and leaves, some covered with a brown bark, and having a tan-colored, woody appearance. The article had been collected by the dealer some time in 1935 in the Bitter Root Mountain range in the State of Montana, and transported to Idaho in his own truck.

LIBELED: 6–30–61, Dist. Idaho.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for rheumatism, prostate trouble, lame back, and bladder trouble.

DISPOSITION: 8–8–61. Default—destruction.

6726. Tafon tablets. (F.D.C. No. 44995. S. No. 91–502 P.)

QUANTITY: 37 cases, each containing 12 180-tablet btls., 83 cases, each containing 13 180-tablet btls., 38 cases, each containing 12 84-tablet btls., 3 cases, each containing 7 84-tablet btls., 12 180-tablet btls., and 57 84-tablet btls., at Denver, Colo.

SHIPPED: During the year 1956, from Hollywood, Calif., by Tafon Distributors, Inc.

LABEL IN PART: "Tafon * * * A Mineral-Water-Soluble Vitamin Dietary Supplement And An Aid to Appetite Appeasement * * * Tafon Distributors, Inc., Los Angeles, Calif. Each Day's Supply (consisting of 12 tablets) Contains: * * * Vitamin B_2 (Riboflavin) 2 mg."

LIBELED: 10–5–60, Dist. Colo.

CHARGE: 502(a)—when shipped, the bottle label contained false and misleading representations that the article was adequate and effective for reducing and for appetite appeasement.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 11–14–60. Default—destruction.

6727. Hadacol capsules. (F.D.C. No. 46055. S. No. 86–804 R.)

QUANTITY: 39 50-capsule btls. and 24 25-capsule btls. at Dallas, Tex.

SHIPPED: Between 6–2–60 and 2–10–61, from Memphis, Tenn., by Plough, Inc. (Hadacol, Inc.).

LABEL IN PART: (Btl.) "Hadacol * * * A Dietary Supplement Capsules * * * Manufactured in the South Exclusively for Hadacol, Inc., Chicago 11, Illinois Each Hadacol Capsule contains * * * Folic Acid, USP 0.25 mg."

ACCOMPANYING LABELING: Leaflet in carton entitled "New! Super Hadacol."

LIBELED: 7–6–61, N. Dist. Tex.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of tiredness, constipation, headaches, grouchiness, washed-out appearance, wornout condition, iron-deficiency anemia, nervousness, and for other purposes.

The article was alleged also to be adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 8–21–61. Default—destruction.

6728. Hadacol capsules. (F.D.C. No. 46029. S. No. 86–802 R.)

QUANTITY: 22 cases, each containing 48 25-tablet ctnd. btls., and 61 cases, each containing 24 50-tablet ctnd. btls., at Dallas, Tex.

SHIPPED: 10–11–60 and 2–14–61, from Memphis, Tenn., by Plough, Inc.

LABEL IN PART: (Btl. and ctn.) "Hadacol * * * A Dietary Supplement Capsules A high-potency concentrate of vitamins and minerals to help overcome the symptoms and dangers that may be caused by an inadequate supply of these vital dietary requirements. Manufactured in the South Exclusively for Hadacol, Inc., Chicago 11, Illinois Each Hadacol Capsule contains * * * Folic Acid, USP 0.25 mg. * * * Directions: Adults: * * * one to three Hadacol Capsules daily."

ACCOMPANYING LABELING: Leaflet in carton entitled "New! Super Hadacol."

LIBELED: 7–6–61, N. Dist. Tex.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of tiredness, constipation, headaches, grouchiness, washed-out appearance, wornout condition, iron-deficiency anemia, nervousness, and for other purposes.

The article was alleged also to be adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 8-21-61. Default—destruction.

6729. Parkelp Sea Kelp, Kal-Kelp iodine tablets, vinegar, and honey. (F.D.C. No. 45504. S. Nos. 50-212/4 R, 50-216/47 R.)

QUANTITY: 100 200-tablet btls., 54 500-tablet btls., 24 850-tablet btls., 125 2-oz. btls., 84 7-oz. btls., and 32 16-oz. btls., of sea kelp; 5 450-tablet btls., and 27 175-tablet btls., of iodine tablets; 12 cases of 24 16-oz. jars, 6 cases of 4 1-gal. jars, and 23 cases of 12 32-oz. jars, of Sterling Cider Vinegar; 29 cases of 12 1-pt. jars, and 7 cases of 12 1-qt. jars of Superl Cider Vinegar; 145 cases of 12 1-lb. jars, 88 cases of 12 2-lb. jars, 47 cases of 12 5-lb. tins, and 6 cases of 24 2½-lb. tins, of honey, at Denver, Colo., in possession of Health Food Sales.

SHIPPED: The sea kelp was shipped on 6-22-60, 8-5-60, 9-1-60, and 1-9-61, from San Pedro, Calif.; the iodine tablets were shipped on 3-14-60 and 11-9-60, from Los Angeles, Calif.; Sterling Cider Vinegar was shipped on 7-5-60, 11-2-60, 1-27-61, and 2-16-61, from New York, N.Y., by Sterling Cider Co., Inc.; Superl Cider Vinegar was shipped on 8-26-60, 9-6-60, and 1-6-61, from Los Alamitos, Calif.; and the honey was shipped on various dates between 3-30-60 and 2-8-61, from Los Angeles, Calif.

LABEL IN PART: (Btl.) "Parkelp Sea Kelp" and KAL * * * Kal-Kelp Natural Iodine Tablets"; (jars) "Sterling Cider Vinegar Full Strength * * * For Dietary Use * * * Made Only by Sterling Cider Co., Inc., Sterling, Mass."; "Superl Cider Vinegar * * * Contents 1 pint [or "1 quart"]"; "Health Food Special Brand * * * Pure Aquinaldo [or "Algarroba," "Alfalfa," "Avocado," "Buckwheat," "Cactus," "Clover," "Eucalyptus," "Mesquite," "Mountain," "Orange," "Safflower," "Sage," "Star Thistle," "Tupelo," or "Wild Flower"] Honey"; and (tins) "Health Food Special Brand * * * 100% Pure Honey Alfalfa [or "Algorraba," "Abucado," "Buckwheat," "Cactus," "Clover," "Eucalyptus," "Mountain," "Orange," "Safflower," "Sage," "Star Thistle," "Wildflower," "Pot O'Gold," or "Wild Honey"]."

ACCOMPANYING LABELING: Books entitled "Arthritis and Folk Medicine," and "Folk Medicine," by D. C. Jarvis; and circulars entitled "Arthritis & Folk Medicine by D. C. Jarvis, M.D." and "Sterling Cider Vinegar."

RESULTS OF INVESTIGATION: The books and circulars were used by the dealer in promotion of the articles. The circulars entitled "Sterling Cider Vinegar" were received from the manufacturer.

LIBELED: 3-17-61, Dist. Colo.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that sea kelp and iodine tablets were adequate and effective as a treatment for and preventive of chronic fatigue, high blood pressure, heart disease and heart attacks, stomach and intestinal ulcers, colitis, arthritis, anxiety, insomnia, anemia, brittle bones, lengthy healing time of fractures, weak and virulent germs in the body, nervous tension, irritability, obesity, frequent sickness, lack of energy and endurance, Bang's disease of cattle, and mental fatigue; and to build and rebuild bodies; for long life; for a "blood wash"; to promote blood and increase hemoglobin; rebuild energy; calm the body; and promote clear thinking; and that cider vinegar and honey were adequate and effective as a treatment for and preventive of stomach

ulcers, intestinal ulcers, colitis, loss of appetite, diseases of tonsils, diseases of teeth, diseases of gall bladder, hyperalkalinity of blood, thin fingernails, senility, influenza, infections of urinary tract, infections of lungs and upper respiratory tract, kidney stones and other troubles, bladder stones, heartburn, gas in stomach, over-activity of children, loss of a will to win, unsocial attitude, pale face, anemia, increased frequency of urination, wet nose, moist eyes, high systolic blood pressure, lameness, paralysis, cancer and Hodgkin's disease, diseases of the skin, common cold, arthritis, digestive disorders, belching, constipation, vomiting and diarrhea from food poisoning, obesity, high blood pressure, chronic fatigue, headaches, infectious disease (fungus type) including typhoid, bronchopneumonia, peritonitis, pleurisy, dysentery, heart disease, heart attacks, diabetes, insomnia, sterility, difficult labor, morning sickness, nervousness, irritability, tension, itching scalp and skin, numbness, cold hands and feet, dizziness, tooth decay, falling hair, breaking fingernails, mental retardation, chickenpox, measles, paranasal sinusitis, sinus seepage, asthma, hayfever, facial neuralgia, retarded growth, pyelitis, thickened blood, ringing in ears, impaired hearing, calluses and corns, slow healing of cuts and bruises, pimples, tic, cramps in muscles, blocked swollen lymph glands, coughs, infant colic, bedwetting, Meniere's syndrome, hangovers, and alcoholism; and to prevent and dissolve calcium precipitation in the body, including deposits in blood vessels, bursae, and joints; to promote proper use of calcium in the body; keep body tissues tender and elastic; preserve good eyesight; prevent tissue degeneration; prevent thick, cloudy fluids; render the urine, skin, and breath acid; increase resistance to disease; increase endurance; improve vital activity of body cells; relieve stress and strain, anxiety, and promote relaxation; eliminate fever in any illness; slow down an overactive sympathetic nervous system; eliminate a "sweet tooth" for food; reduce and eliminate bleeding from cuts, hemorrhoids, in bowel movements, in urine, from the nose, post-operatively, during surgery, and excessive menstrual flow with passage of clots; make better bone marrow; increase hemoglobin; prevent wrinkles; retard aging, promote vigor, longevity, and good health from the cradle to the grave; and for weight reduction without dieting; and Sterling Cider Vinegar, 502(a)—when shipped and while held for sale, the accompanying labeling (circulars entitled "Sterling Cider Vinegar") contained false and misleading representations that the article was adequate and effective for reducing body weight.

The libel alleged also that the honey was misbranded under the provisions of the Act relating to foods, as reported in notices of judgment on foods.

DISPOSITION: 8–3–61. Consent—claimed by Daniel A. Nidess, t/a Health Food Sales Co., and released for relabeling. The literature was delivered to the Food and Drug Administration.

6730. Concentrated sea water. (F.D.C. No. 45879. S. No. 23–836 R.)

QUANTITY: 30 btls. at Salina, Kans.

SHIPPED: 10–10–60, from Lakeland, Fla., by the Florida Sea Brine Laboratories, Inc.

LABEL IN PART: (Btl.) "This bottle contains 64 drams of highly concentrated 100% Pure Atlantic Ocean Water 8 Fl. Oz. Sea Brine For Better Health Recommended dosages for ages 9 to 109 – 1 teaspoon per day in Fruit or Vegetable Juice, Tap Water - Use like seasoning in Cooked Foods. Contains Chloride – Sodium – Sulfate – Magnesium – Calcium – Potassium Salt Free Dietetics Consult Your Doctor Before Using Contents of This Bottle

Processed and Distributed by the Florida Sea Brine Laboratories, Inc. P.O. Box 1733 Lakeland, Florida."

ACCOMPANYING LABELING: Placard reading in part "Introductory Offer Sea Brine * * * Florida Sea Brine Laboratories, Inc., Lakeland, Florida" and leaflet reprint of a newspaper article entitled "Worry Clinic Sea Water Can Help Prevent Disease, By George W. Crane, Ph. D., M.D."

LIBELED: 5–16–61, Dist. Kans.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for or preventive of cancer, diabetes, arthritis, gray hair, baldness, plus dozens of other complaints not due to germs or a virus; that it was a "chemical smorgasbord" for body glands, thereby providing for the proper function of the pancreas, thyroid, adrenals, stomach, bone marrow, gonads, etc., and other organs to guard health and prevent sickness; and that through use of the article one may achieve better health.

DISPOSITION: 9–29–61. Default—destruction.

6731. Ocean Aid ocean water. (F.D.C. No. 45785. S. No. 17–115 R.)

QUANTITY: 1 case containing 18 8-oz. btls., and 341 cases containing 24 8-oz. btls. each, at Zionsville, Ind.

SHIPPED: 12–27–60 and 1–25–61, from Vero Beach, Fla., by Ocean Concentrate, Inc.

LABEL IN PART: (Btl.) "Ocean Aid to Better Health Concentrated Ocean Water 47 Water Soluble Minerals Many of these minerals are missing or seriously reduced from our farmland, so our meats and potatoes, vegetables and fruits are often lacking in these minerals that are so essential to our health and well-being * * * Manufactured by Ocean Concentrate, Inc., P.O. Box 206 Vero Beach, Florida."

ACCOMPANYING LABELING: Placards entitled "Ocean Aid to Better Health Concentrated Ocean Water" and a number of labels similar to the bottle label described above.

LIBELED: 5–17–61, S. Dist. Ind.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective for better health; that it was essential to health and well-being, and for the treatment of diseases of man; and that foods, as consumed, were lacking in all the trace minerals that were found in the article.

DISPOSITION: 8–2–61. Default—destruction.

6732. Coldene vitamin tonic with iron. (F.D.C. No. 45768. S. No. 38–020 R.)

QUANTITY: 360 12-btl. cases at Philadelphia, Pa.

SHIPPED: 6–22–60, from Cranbury, N.J., by Pharma-Craft Corp.

LABEL IN PART: "Coldene Vitamin Tonic with Iron * * * Each fluid oz. (2 Tablespoonfuls) contains: * * * Riboflavin (B_2) 4 mg. * * * Pharma-Craft Corporation, Distrs. Cranbury, N.J."

ACCOMPANYING LABELING: Leaflet in carton entitled "Coldene Liquid Cold Medicine."

LIBELED: 5–3–61, E. Dist. Pa.

CHARGE: 502(a)—when shipped and while held for sale, the label of the article contained false and misleading representations that the article was

adequate and effective as a preventive of and treatment for rundown conditions, and for use in convalescence from colds, flu, and similar illness; and the name of the article "Coldene Vitamin Tonic with Iron," and label statement "therapeutic tonic" were misleading since the article was not adequate and effective as a "Vitamin tonic," since it contained the vitamin B grouping and methionine, and not vitamins in general.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION : 9–13–61. Default—destruction.

6733. Verdogen capsules. (F.D.C. No. 45843. S. No. 62–098 R.)

QUANTITY: 149 btls., consisting of 2 180-capsule btls., 63 90-capsule btls., and 84 30-capsule btls., at Kansas City, Mo., in possession of Dayco Products Co.

SHIPPED: In the early part of 1960, from Kalamazoo, Mich.

LABEL IN PART: "550 mg. in Capsules Each Capsule Verdogen Natural Chlorophyllins Vitamins B_1 and B_6 Distributed by Dayco Products Division of Dayco Laboratories, Inc., North Kansas City, Missouri."

RESULTS OF INVESTIGATION: The article had been repacked by the dealer from bulk stock shipped as described above.

LIBELED: On or about 6–23–61, W. Dist. Mo.

CHARGE: 502(a)—while held for sale, the label of the article contained false and misleading representations that the article was adequate and effective as a treatment for difficult breathing caused by respiratory ailments and asthmatic conditions, anemia, high-altitude dizziness, headache and nausea attributed to lack of oxygen in the blood.

DISPOSITION: 8–10–61. Default—destruction.

6734. Utopia Home Mineral Bath. (F.D.C. No. 46268. S. No. 57–524 R.)

QUANTITY: 25 cases, each containing 12 ctns. of 21 3-oz. envelopes, at Billings, Mont.

SHIPPED: 6–16–61, from Seattle, Wash., by Comfort Research, Inc.

LABEL IN PART: (Envelope) "Utopia Home Mineral Bath Ingredients: Aluminum Sulfate, Magnesium Sulfate, Magnesium Carbonate, Sodium Bicarbonate, Sodium Sulfate, Potassium Sulfate, Sodium Chloride, Sodium Borate. * * * Manufactured by Comfort Research, Inc., Seattle, Washington."

LIBELED: 8–23–61, Dist. Mont.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective, because of its mineral salt composition, as a treatment for relieving pain due to arthritis, rheumatism, neuritis, nervous tension, and muscular discomforts.

DISPOSITION: 9–22–61. Default—destruction.

6735. Arthritis treatment. (F.D.C. No. 45473. S. No. 67–347 R.)

QUANTITY: 594 boxes of *Formula No. 161;* 43 boxes of *Formula 131;* 74 100-tablet btls. of *Noxid;* 191 120-tablet btls. of *Noxid #1 Laxative,* at Arlington, Tex., in possession of Dixon Laboratories.

SHIPPED: The ingredients for *Formula No. 161* and *Formula 131,* were shipped in December 1960, from New York, N.Y.; *Noxid tablets* were shipped on an

unknown date in 1960, from Memphis, Tenn.; and the *Noxid #1 Laxative* was shipped on an unknown date in 1960, from Long Island, N.Y.

LABEL IN PART: "Formula No. 161 Composed of Cascara Sagrada, Uva Ursi, Black Cohosh, Bittersweet, Poke Root, Senna Pods, Cramp Bark, Wahoo Bark, Hydrangea, Prickly Ash Berries, Fennel Seed, Wintergreen Leaves, Bog Bean, Black Root, Virginia Snake Root, Indian Physic. Tonic and Analgesic * * * Warning * * * Dixon Laboratories * * * P.O. Box 29, Arlington, Texas Contents Not Less than 3 Ozs. When Packed"; "Formula 131 Diuretic Composed of Saw Palmetto Berries, Juniper Berries, Buchu, Uva Ursi, Marshmallow Root, Trailing Arbutus, Couch Grass, Crawl Grass, Pichi Tops, Celery Seed. Dose * * * Dixon Laboratories * * * 3 Ozs."; "100 Tablets Noxid Tablets Each Tablet Contains: Vitamin D (Irradiated Ergosterol) 10,000 Units Colchicine 1/200 Grain Colchicum 1/20 Grain Caution: * * * Prepared For Dr. Dixon's Herbal Laboratory, 300 Oakwood Lane P.O. Box 29, Arlington, Texas * * * Indications: Usual Dose: * * * 1550373"; and "120 Tablets Noxid #1 Laxative Each Tablet Contains The Following Ingredients: Senna Leaves, Aloin Powder, Senna Pods, Celery Seed, Black Root, Cascara Sagrada, Mandrake, Poke Root, Buckthorn, Licorice, Liverwort, Marshmallow Root, Fennel Seed, Malva Leaves. Distributed by: The Noxid Co., 507 Oakwood Lane, Arlington, Texas Dosage: * * * Caution: * * * 16254."

ACCOMPANYING LABELING: Leaflets entitled "Professional Products List."

RESULTS OF INVESTIGATION: The *Formula No. 161* and *Formula 131* were manufactured by the dealer. The leaflets were printed at the request of the dealer and used in promoting sales of the articles.

LIBELED: 3–20–61, N. Dist. Tex.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the articles were adequate and effective as a treatment for arthritis.

DISPOSITION: 10–31–61. Default—destruction.

6736. ClearAir electronic air purifier device. (F.D.C. No. 44998. S. No. 6–613 R.)

QUANTITY: 39 individually cartoned devices at Boston, Mass.

SHIPPED: Between 7–1–60 and 8–17–60, from New York, N.Y., by Radio Merchandise Sales, Inc.

LABEL IN PART: (Ctn.) "ClearAir Portable Electronic Air Purifier Model CA–32 * * * Radio Merchandise Sales, Inc., Bronx 62, N.Y."

ACCOMPANYING LABELING: Leaflet in carton, entitled "Operating Instructions for Your Clear Air."

RESULTS OF INVESTIGATION: Investigation indicated the article to be a portable table model-type cabinet containing an air filter, electric fan and two ultraviolet lamps. In operation, this unit reportedly circulated room air so that it was exposed to the ultraviolet lamps and was passed through the filter back into the room.

LIBELED: 10–6–60, Dist. Mass.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for relieving hay fever, sinus conditions, allergy conditions, and asthma, and for providing better health.

DISPOSITION: 11–14–60. Default—destruction.

6737. Electric food grinder-blender device. (F.D.C. No. 46411. S. No. 27–210 R.)

QUANTITY: 53 devices at Burbank and Gardena, Calif., in possession of Live Food Products Co.

SHIPPED: On or about 6–29–61, from Jersey City, N.J.

ACCOMPANYING LABELING: Form letter beginning "Dear Friend and Student" on letterhead of "Paul C. Bragg"; order blank reading in part "Live Foods for Life! Live Food Products Company * * * Home of Bragg Products"; and brochure entitled "Discover the Goodness of Natural Foods Good Health Begins With Proper Eating * * * Moulinex."

RESULTS OF INVESTIGATION: Examination showed the article to be an electrically driven food grinder-blender.

The dealer had prepared the form letter and order blank and distributed them to customers by mail or by hand.

LIBELED: 9–1–61, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the accompanying labeling of the device contained false and misleading representations that use of the article was an adequate and effective treatment for overcoming tension and anxiety; increasing strength, endurance, and energy; creating a rich, red, powerful bloodstream, and for preventing colds.

DISPOSITION: 9–29–61. Default—one device delivered to the Food and Drug Administration; remainder destroyed.

6738. Facialift device. (F.D.C. No. 44862. S. No. 25–303 R.)

QUANTITY: 9 devices, enclosed in a "jewel box" type of container with a 6-oz. btl. of lotion, at Phoenix, Ariz.

SHIPPED: Between 10–1–59 and 8–18–60, from Beverly Hills, Calif., by Facialift, Div. of WilloSlim, Inc.

LABEL IN PART: (Device) "Facialift * * * Facialift Division of WilloSlim, Inc., Beverly Hills, Calif." and (lotion) "Facialift Lotion."

ACCOMPANYING LABELING: Brochures entitled "Facialift Your Key to a Bright New World"; training manuals entitled "Facialift Sales Training Manual"; single sheets reading in part "Facialift Weekly Report" and "Technical Data on Our Facialift Instrument"; display cards reading in part "For the one area you cannot hide"; folders reading in part "For Your Face and Throat" and "Facialift an Invitation"; single sheets reading in part "Facialift made the difference" and "Electro-Therapy Can Firm Facial Tissue"; cards reading in part "I take great pleasure in announcing," "Facialift Owner Register," and "I understand that I have been given"; leaflets reading in part "She Uses Facialift because" and "McCalls * * * She uses Facialift"; cards reading in part "I am interested in learning about"; single sheets entitled "Release"; card entitled "Registration Card"; photocopy reprint entitled "Fig. 377-Muscles of the head, face and neck"; newspaper tear sheets of an article entitled "Sagging Face and Neck Firmed by Facialift"; magazine dated Nov. 6, 1959 containing advertisement for *Facialift* on p. 34; and recordings used for training sales personnel.

RESULTS OF INVESTIGATION: Investigation showed that the article was a portable carrying case containing a 9-volt battery-operated transistor circuit supplying 45 electrical pulsations per minute to an applicator containing two electrodes about ¾ inch square, imbedded in plastic, with about a ¼ inch gap between electrodes.

LIBELED: 8–18–60, Dist. Ariz.

CHARGE: 502(a)—when shipped, the label and accompanying labeling of the device contained false and misleading representations that the article was an adequate and effective treatment for firming flabby muscles and sagging contours; improving circulation to flush out accumulated fatty deposits and body fluids; correcting "double chin" and removing wrinkles; upgrading the quality of muscle fiber to provide muscle tone; removing "crow's feet" from around the eyes; regaining youthful beauty; and providing a "facial lift."

DISPOSITION: 6–9–61. Consent—claimed by the shipper and released under bond to be brought into compliance with the law.

6739. Samson Massage-A-Belt. (F.D.C. No. 45116. S. No. 16–018 R.)

QUANTITY: 60 devices at Cincinnati, Ohio, in possession of Checker Stores.

SHIPPED: 9–7–60, from New York, N.Y., by Frank M. Katz, Inc.

LABEL IN PART: (Ctn.) "Samson Massage-A-Belt Healthful Slenderizing 'It's New!' * * * Portable. * * * Samson United Corp. of N.Y. * * * Long Island City 1, N.Y."

ACCOMPANYING LABELING: Pamphlets in device carton entitled "How to Use your Massage-A-Belt," "Enjoy Controlling Your Calories"; and newspaper tear sheets entitled "Helps You Stay Healthy, Youthful, Stylishly Slim."

RESULTS OF INVESTIGATION: Some of the newspaper tear sheets were prepared by the dealer, and some were received by the dealer from the shipper.

The article consisted of a foot platform to which was attached an upright tubular-shaped standard supporting an electric motor housing. A web belt was attached to opposite sides of the motor housing. In operation the belt was to be placed about the girth of a part of the human body, and the vibrations of the motor reportedly were transmitted through the web belt to massage the area in contact with the belt.

LIBELED: 11–25–60, S. Dist Ohio.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was an adequate and effective treatment for firming and toning muscles to prevent flabbiness; activating muscles to support and shape the figure; firming the buttocks and hips; resisting flabbiness; relieving common backache; keeping one healthy, youthful, and slim; improving posture; and lifting the female bustline.

DISPOSITION: 10–9–61. Default—a number of the devices were delivered to local hospitals, after destruction of their accompanying labeling, and the remainder of the devices, with their accompanying labeling, were delivered to the Food and Drug Administration.

DRUG FOR VETERINARY USE

6740. Clay (feed supplement). (F.D.C. No. 45746. S. No. 52–261 R.)

QUANTITY: 450 100-lb. bags at Denver, Colo.

SHIPPED: The article was shipped in bulk lots, on 1–29–61, from Coyote Wells, Calif.

LABEL IN PART: "The Natural Mineral (not synthetic) feed supplement M 27 for all livestock. Directions For Feeding * * * Guaranteed Analysis Not Less Than: Calcium Oxide 5.14% Magnesium Oxide 2.46% Sodium Oxide .93% Potassium Oxide .41% Also Ferrous, Ferric, Manganese, Chromium, Strontium, Barium, Vanadium, Copper, Zirconium, Nickel, Cobalt, Titanium,

Arsenic, and Lead Oxides. Carbon Dioxide, Sulphuric, Phosphoric and Boric Anhydrides. Fluorine, Chloride, Calcium Carbonate and Sodium Chloride. All contained in a base of Aluminum and Silicon Oxides. Imperial Minerals, Inc., Glendale, California Imperial Minerals Distributing Co., 9371 Ellen Ct., Denver 29, Colorado."

ACCOMPANYING LABELING: Leaflets entitled "Directions for Feeding M 27," and approximately 2,375 extra bags labeled as described above.

RESULTS OF INVESTIGATION: After shipment of the article, as described above, the article was ground and packed in bags furnished to the packer by Imperial Minerals Distributing Co. (Samuel F. Burkhalter). The above-mentioned leaflets were received at Denver, Colo., on an unknown date and were used by Samuel F. Burkhalter in promoting sales of the article.

LIBELED: 5–4–61, Dist. Colo.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for scours and coccidiosis in animals.

The article was alleged also to be misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods, No. 27787.

DISPOSITION: 5–23–61. Consent—claimed by Samuel F. Burkhalter, t/a Imperial Minerals Distributing Co., Thornton, Colo., and released under bond for relabeling. On 9–1–61, pursuant to stipulation by the parties, the decree of 5–23–61 was amended to provide that the claimant and all his employees and associates should at no time sell or promote the released article in writing, advertising, or orally for therapeutic purposes or for furnishing significant mineral nutrition.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 6701 TO 6740

PRODUCTS

[1] (6715) Injunction issued.
[2] (6703) Seizure contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (6715) Injunction issued.
[2] (6703) Seizure contested.

[1] (6715) Injunction issued.
[2] (6703) Seizure contested.

U.S. GOVERNMENT PRINTING OFFICE:1962

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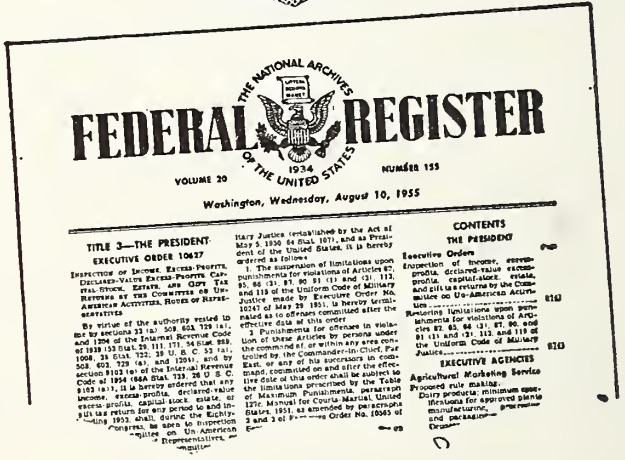

THE NATIONAL ARCHIVES

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OF THE UNITED STATES 1934

VOLUME 20 NUMBER 155

Washington, Wednesday, August 10, 1955

TITLE 3—THE PRESIDENT

EXECUTIVE ORDER 10627

INSPECTION OF INCOME, EXCESS-PROFITS, DECLARED-VALUE EXCESS-PROFITS, CAPITAL STOCK, ESTATE, AND GIFT TAX RETURNS BY THE COMMITTEE ON UN-AMERICAN ACTIVITIES, HOUSE OF REPRESENTATIVES

By virtue of the authority vested in me by sections 33 (a) 368, 728 (a), and 1204 of the Internal Revenue Code of 1939 (53 Stat. 29, 111, 172, 54 Stat. 958, 1008, 35 Stat. 722, 28 U. S. C. 33 (a), 508, 603, 729 (a), and 1204), and by section 8103 (a) of the Internal Revenue Code of 1954 (68A Stat. 733, 26 U. S. C. 8103 (a)), it is hereby ordered that any income, excess-profits, declared-value excess-profits, capital stock, estate, or gift tax return for any period to and including 1953, shall, during the Eighty-[illegible] Congress, be open to inspection by the Committee on Un-American Activities of the House of Representatives, or [illegible]

Harry Justice established by the Act of May 5, 1950 (64 Stat. 107), and as President of the United States, it is hereby ordered as follows:

1. The suspension of limitations upon punishments for violations of Articles 87, 93, 86 (3), 87, 90, 91 (1) and (3), 113, and 119 of the Uniform Code of Military Justice made by Executive Order No. 10247 of May 29, 1951, is hereby terminated as to offenses committed after the effective date of this order.

2. Punishments for offenses in violation of these Articles by persons under the command of, or within any area controlled by the Commander-in-Chief, Far East, or any of his successors in command, committed on and after the effective date of this order shall be subject to the limitations prescribed by the Table of Maximum Punishments, paragraph 127c, Manual for Courts-Martial, United States, 1951, as amended by paragraphs 2 and 3 of Executive Order No. 10565 of [illegible]

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THE PRESIDENT

Executive Orders

Inspection of income, excess-profits, declared-value excess-profits, capital-stock, estate, and gift tax returns by the Committee on Un-American Activities 8103

Restoring limitations upon punishments for violations of Articles 87, 93, 86 (3), 87, 90, and 91 (1) and (3), 113, and 119 of the Uniform Code of Military Justice 8103

EXECUTIVE AGENCIES

Agricultural Marketing Service

Proposed rule making:

Dairy products; minimum specifications for approved plants; manufacturing, processing, and packaging [illegible]

The Federal Register publishes the full text of Presidential Proclamations and Executive Orders, and the rules and regulations of the various Departments of the Federal Government.

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6741–6780

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve seizure proceedings in which decrees of condemnation were entered after default or consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *October 24, 1962.*

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*For omission of, or unsatisfactory, ingredients statements, see No. 6773; an imitation of, and sale under name of, another drug, No. 6757; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 6777; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 6768; cosmetics, actionable under the drug provisions of the Act, Nos. 6777, 6778.

658982—62——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6741–6780

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, or its quality or purity fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted in whole or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(c), a word, statement, or other information required by, or under authority of, the Act to appear on the label or labeling of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear, in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f)(1), the labeling of the article failed to bear adequate directions for use; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

6741. Ferbetex tablets. (F.D.C. No. 45801. S. No. 32–280 R.)

QUANTITY: 287 50-tablet btls. at Santurce, P.R.

SHIPPED: 2–28–61, from Los Angeles, Calif., by Strand Pharmacal Corp.

LABEL IN PART: "Ferbetex (Improved) Formula Per Tablet * * * Folic Acid 0.4 mg. * * * 50 Tablets Strand Pharmacal Corporation, Los Angeles, California * * * Dosis: 2 Tablets with Meals or as Prescribed."

LIBELED: 5–16–61, Dist. P.R.; amended libel 5–23–61.

CHARGE: 502(j)—when shipped, the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof, since the article, under the directions for use, would supply 2.4 milligrams of folic acid daily.

DISPOSITION: 6–22–61. Default—destruction.

6742. Armatinic liquid. (F.D.C. No. 45807. S. Nos. 32–281/82 R.)

QUANTITY: 180 4-oz. btls. and 127 8-oz. btls. at Santurce, P.R.

SHIPPED: 12–31–60 and 2–8–61, from Kankakee, Ill., by Armour Pharmaceutical Co.

LABEL IN PART: (Btl.) "Armatinic Liquido—Cada 29.57 ML Contiene—Acido Folico 2 mg.—Armour Pharmaceutical Company Kankakee, Illinois."

LIBELED: 5–25–61, Dist. P.R.

CHARGE: 502(j)—when shipped, the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling, since, under the label directions for use, 2 tablespoonfuls twice a day (1 lot) and 2 teaspoonfuls twice a day (second lot), the article would supply 4 mg. and 1.3 mg. of folic acid daily respectively.

DISPOSITION: 7–20–61. Default—destruction.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUG FOR HUMAN USE

6743. Biphetamine-T 12½ and Biphetamine-T 20. (F.D.C. Nos. 46260, 46264. S. Nos. 97–215 R, 97–217/18 R.)

QUANTITY: 33 50-capsule btls. of 12½-mg. capsules; 49 50-capsule btls. of 20-mg. capsules; 5 cases, each containing 12 50-capsule btls. of 12½-mg. capsules; and 4 cases, each containing 12 50-capsule btls. of 20-mg. capsules, at Pittsburgh, Pa.

SHIPPED: Between 4–14–61 and 6–30–61, from Rochester, N.Y., by Strasenburgh Laboratories, Div. of Wallace & Tiernan, Inc.

LABEL IN PART: "Biphetamine T–12½ [or "T–20"] * * * Strasenburgh Laboratories Division Wallace & Tiernan, Inc., Rochester, N.Y."

ACCOMPANYING LABELING: File card entitled "Biphetamine-T" and a brochure entitled "The Clinical Importance of Weight Reduction in Exogenous Obesity."

LIBELED: 8–23–61, W. Dist. Pa.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the drug, namely, the file card entitled "Biphetamine-T," contained false and misleading representations that the article reduced the insulin requirement in diabetes, reduced the nitroglycerin requirement in arteriosclerosis, and reduced the blood pressure in hypertension; 502(f)(1)—the labeling of the article failed to bear adequate directions for use and it was not exempt from the requirement that the article bear such directions for use, since the promotional material for the new drug was not the same as, or substantially the same as, the labeling authorized by the effective new drug application; 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since the effective new drug application filed with respect to the article did not apply to the conditions for which the article was promoted to the medical profession, namely,

(a) in the physician's file card entitled "Biphetamine-T," distributed to physicians, the drug was represented as being capable of reducing the insulin requirement in diabetes, of reducing the nitroglycerine requirement in arteriosclerosis, and of reducing blood pressure in hypertension; and

(b) in the brochure entitled "The Clinical Importance of Weight Reduction in Exogenous Obesity" the drug was offered for diabetes, arteriosclerotic heart disease, hypertension, and ulcers;

which labeling representations differed materially from the labeling claims permitted by the effective new drug application.

DISPOSITION: 10–13–61. Default—destruction.

DRUG FOR VETERINARY USE

6744. Iro-Jex injectable. (F.D.C. No. 45628. S. Nos. 61–044/45 R.)

QUANTITY: 226 30-cc. btls. and 607 100-cc. btls. at Kansas City, Mo.

SHIPPED: 2–7–61 and 3–22–61, from Los Angeles, Calif.

LABEL IN PART: "Iro-Jex Injectable Iron-Arsenic Solution each 2 cc contains: Ferric Cacodylate 1 Gr. Copper Sulfate 1/100 Gr. * * * Suggested dosage: 2 cc given intramuscularly or intravenously—distributed by the National Laboratories Corp. Kansas City."

RESULTS OF INVESTIGATION: When shipped, the labeling offered the drug for human use. The dealer relabeled the article for veterinary use.

LIBELED: On or about 4–17–61, W. Dist. Mo.; amended libel on or about 5–17–61.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 7–12–61. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6745. Vigo Forte tablets, Altocaps capsules, and vitamin B_{12} and B_1 injection. (F.D.C. No. 45900. S. Nos. 32–274/77 R.)

QUANTITY: 19 50-tablet btls. of *Vigo Forte tablets;* 18 20-capsule btls. of 50-mg. *Altocaps capsules;* 20 20-capsule btls. of 100-mg. *Altocaps capsules;* and 79 10-cc. vials of *vitamin B_{12} and B_1 injection,* at San Juan, P.R.

SHIPPED: Between 10–1–60 and 11–17–60, from Newark, N.J., by Benson Pharmacal Corp.

LABEL IN PART: (Btl.) "Vigo Forte * * * Testosterona 2 mgm. Vitamin E 10 mgm. Extracto de damiana 60 mgm. Extracto de nuez vomica 5 mgm. Clorhidrato de yohimbine 5 mgm. Puerto Rico Drug * * * San Juan, P.R.–Distributors"; "Benson Altocaps 50 Mg. [or "100 Mg."] Each capsule contains * * * Vitamin E (from d-alpha Tocopheryl Acetate Concentrate, N.F.) Directions: One to six capsules daily * * * Benson Pharmacal Co., Inc., New York, N.Y."; and (vial) "Multiples Dosis 10 cc Frasco Vitaminas B_{12} y B_1 Cada cc contiens vitamina B_{12} 1000 mcgm. Vitamina B_1 100 mg. * * * intramuscular Benson Pharmacal Corp., Newark, N.J."

LIBELED: 5–29–61, Dist. P.R.

CHARGE: *Altocaps capsules,* 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for habitual abortion, ovarian failure, muscular dystrophy, and amyotrophic lateral sclerosis.

Vigo Forte tablets and vitamin B_{12} and B_1 injection, 503(b)(4)—the articles were drugs subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without a prescription."

DISPOSITION: 7–20–61. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE*

6746. Insta-Pep tablets. (F.D.C. No. 43373. S. No. 82–806 P.)

QUANTITY: 17 cases of 36 50-tablet btls. and 10 cases of 72 25-tablet btls. at North Kansas City, Mo., in possession of Katz Drug Co.

SHIPPED: Between 6–24–59 and 8–26–59, from New York, N.Y., by Drug Research Corp.

LABEL IN PART: "Insta-Pep with Dynamol and 'Vitamin Feed' for prolonged Vitamin-Mineral Release A high potency therapeutic Vitamin-Iron formula * * * Each tablet contains: Thiamine Chloride (Vit. B_1) 15.0 mg. Riboflavin (Vit. B_2) 6.0 mg. Cobalamin Concentrate (Vit. B_{12} Activity) 3.0 mg. Nicotinic Acid 30.0 mg. *Calcium Pantothenate 3.0 mg. *Choline Bitartrate 10.0 mg. Folic Acid 0.1 mg. *Inositol 20.0 mg. *dl-Methionine 20.0 mg. Iron (from Ferrous Sulfate) 30.0 mg. Ascorbic Acid (Vit. C) 90.0 mg. Pyridoxine Hydrochloride (Vit. B_6) 0.5 mg. Whole Liver Desiccate 25.0 mg. Calcium (from Dicalcium Phosphate) 30.0 mg. Phosphorus (from Dicalcium Phosphate) 20.0 mg. Sodium Acid Phosphate 100.0 mg. *Vitamin E (from d-alpha Tocopheryl Acid Succinate) 1.0 I.U. Iodine (from Potassium Iodide) 0.1 mg. Copper (from Cupric Sulfate) 1.25 mg. *Manganese (from Manganese Sulfate) 0.85 mg. *Cobalt (from Cobalt Sulfate) 0.04 mg. Potassium (from Potassium Sulfate) 0.65 mg. Magnesium (from Magnesium Sulfate) 0.50 mg. together with factors natural to liver content Caffeine Alkaloid Anhydrous 3.0 gr. Sole Distributors: Drug Research Corp. New York, N.Y."

ACCOMPANYING LABELING: Newspaper tear sheet, reading in part "Insta-Pep Stops Rapid Vitamin-Mineral Loss in Your Body! Fights Fatigue in 20 minutes! The Kansas City Star, Sunday, August 2, 1959."

RESULTS OF INVESTIGATION: The newspaper tear sheets were displayed with the article at various Katz Drug Stores in Kansas City, Mo.

LIBELED: 9–25–59, W. Dist. Mo.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was capable of providing instant pep; was the first new development in the vitamin field in over 20 years; stopped rapid vitamin-mineral loss in the body; fought fatigue in 20 minutes; stopped "vitamin let-down" even if tense, worried, or working under pressure; that feeling of fatigue as a result of tensions, worry and working under pressure is due to "vitamin let-down"; that chronic fatigue not aided by other vitamin preparations would be aided by *Insta-Pep tablets* to the extent that users would never feel tired any more; that *Insta-Pep tablets* contained a new, remarkable, amazing antifatigue factor; that "Dynamol" was a new "Vitamin-Mineral" discovery; that *Insta-Pep tablets* contained all necessary vitamins-minerals to build up the body; that the body throws off

*See also No. 6743.

most essential vitamins and minerals unless offered at the moment the body needs them; that vitamin preparations, other than *Insta-Pep tablets*, are passed out of the system in 3–4 hours; that *Insta-Pep tablets* released all the vitamins and minerals the body needs at the moment the body needs them; that tired feelings and rundown conditions are caused by vitamin deficiencies due to devitalized modern food, stress, conditions, or waste of vitamins by the body; that modern food is devitalized; that *Insta-Pep tablets* contained sufficient quantities of all the essential vitamins and minerals so that one tablet per day was an adequate cure and treatment for all vitamin and mineral deficiencies; that up to 80 percent of most vitamins and minerals in vitamin-mineral preparations, other than *Insta-Pep tablets*, are gone from the body in 4 hours; that the body may be vitamin-starved in less than 4 hours after taking vitamin preparations other than *Insta-Pep tablets;* that *Insta-Pep tablets* would materially increase physical strength of persons taking it; that *Insta-Pep tablets* would significantly increase mental alertness and ability to think more clearly; that *Insta-Pep tablets* would provide more vitamin-mineral benefits than higher potency formulas; that *Insta-Pep tablets* would relieve any normal fatigue in 20 minutes; that *Insta-Pep tablets* contained all vitamins and minerals necessary to build up the entire system; that the effect of the vitamins and minerals in *Insta-Pep tablets* was superior to all other vitamin-mineral preparations because it contained "Dynamol"; that the effect of the vitamins and minerals in *Insta-Pep tablets* was superior to all other vitamin-mineral preparations because it was contained in a sustained-action pill; that the use of "Dynamol" to relieve fatigue was new and one of the latest scientific developments; that use of *Insta-Pep tablets* would overcome the tired, rundown feeling of persons who take single dose vitamin preparations and still feel tired and rundown; that *Insta-Pep* was the first and only sustained release vitamin preparation; that *Insta-Pep tablets* gave 3 times the minimum daily adult requirements of all essential vitamins; that *Insta-Pep tablets* contained high-potency, therapeutic amounts of all vitamins and minerals essential to good health; that *Insta-Pep tablets* contained therapeutic amounts of all essential vitamins and minerals to be effective to adequately treat and cure diseases and symptoms due to any vitamin and mineral deficiency of long standing by taking one pill per day; that *Insta-Pep tablets* would help the body maintain essential levels of all necessary vitamins and minerals by taking one pill per day; that it was a multivitamin and mineral preparation containing all of the known vitamins and minerals essential to health; 502(a)—the labeling of the article contained statements which were misleading in that it failed to reveal that "Dynamol" is caffeine, and that each tablet contained the caffeine equivalent of two cups of coffee per day, and that relief of fatigue, if any, in twenty minutes was due to the action of the caffeine and not to the vitamin-mineral content; and that the article did not contain two essential vitamins, A and D, and did contain nutritionally insignificant amounts of the essential minerals, calcium and phosphorus; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment of vitamin and mineral deficiencies.

DISPOSITION: On 11–25–59, Drug Research Corp. appeared as claimant and filed an answer denying that the article was misbranded. Thereafter, the claimant filed a motion for the transfer of the case for trial to the Eastern District of New York and, on 2–1–60, the court handed down the following decision:

MEMORANDUM AND ORDER

RIDGE, *District Judge:* "This is an action in libel, seeking forfeiture of certain drugs allegedly misbranded and shipped in interstate commerce in violation of the Federal Food, Drug & Cosmetic Act, (*21 U.S.C.A. 301, etc.*).

"Pursuant to the provisions of *21 U.S.C.A., Section 334(a)*, defendant has moved for an order transferring this case for trial to the United States District Court for the Eastern District of New York, at Brooklyn. The parties have been unable to stipulate for such removal because the Government urges that a transfer to the Eastern District of New York would be injudicious in light of the congestion of the court docket in that district. The Government suggests, instead, that the action be transferred to the District of New Jersey, a 'district of reasonable proximity to the claimant's principal place of business' where an early trial of this case may be had.

"Claimant's principal place of business is located in the Southern District of New York. The Court takes judicial notice of the fact that court in the Eastern District of New York is held at Brooklyn; court in the District of New Jersey is held at Newark; and that it is approximately an equal distance from both these places to Manhattan, in the City of New York, where court is held in the Southern District of New York. The 'Annual Report of the Director of the Administrative Office of the United States Courts,' dated September, 1959, reflects the comparative docket conditions and time interval involved in the disposition of civil cases filed and terminated in such jurisdiction during the fiscal year ending June 30, 1959.

"From an examination of Table C–5, C–5A, and C–6, appended to said report, it is revealed that the congestion of the docket in the Eastern District of New York is one of the heaviest in all the United States District Courts in the country; that the median time for the termination of business of cases filed in that district is one of the longest in the country; while the median time for disposition of business in the District of New Jersey is well below the average of all the other districts.

"Nothing in *Section 334(a)*, *supra*, militates or prevents the transfer of this case to the District of New Jersey, a 'district in reasonable proximity to the claimant's principal place of business.' We can perceive no prejudice to claimant by such a transfer. Claimant will not be prejudiced in securing the attendance of any witnesses found in, or residents of, the Southern District of New York, nor will it be prejudiced by earlier trial of this case in the District of New Jersey, than if this case is transferred to the Eastern District of New York, which is a matter for consideration in the interest of justice.

"THEREFORE, IT IS ORDERED BY THE COURT that the Clerk transfer all papers on file in this case to the United States District Court for the District of New Jersey, at Newark, New Jersey, for further proceedings herein."

Following the removal of the case to the District of New Jersey the Government filed written interrogatories. The claimant filed answers to the interrogatories after which the Government filed a motion to compel more complete answers to the interrogatories. Such motion was granted by the court on 9–23–60. The claimant failed to file further answers to the interrogatories and, on 11–14–60, the court entered a default decree of condemnation and destruction.

6747. Various prescription drugs. (F.D.C. No. 46265. S. Nos. 97–714/15 R, 97–717 R.)

QUANTITY: Various quantities of prescription drugs and 1 25-tablet btl. labeled *Deronil*, at Corry, Pa., in possession of Corry Pharmacy.

SHIPPED: On unknown dates, from various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample" or similar wording.

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs originally intended for use as samples for physicians and others lawfully engaged

in dispensing prescription drugs, and bearing labels containing the words "Professional Sample," or similar wording, and the names and addresses of manufacturers, packers, or distributors located outside the State of Pennsylvania. The bottle labeled *Deronil* had been repacked by the dealer.

LIBELED: 8–18–61, W. Dist. Pa.

CHARGE: 502(a)—while held for sale, the words "Professional Sample," and similar wording on the labels of a number of articles, were false and misleading as applied to these articles then in possession of a repacker and intended for sale, and not then intended for use as "complimentary – not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; and 502(f)(1)—the labeling of the article of drug labeled *Deronil* failed to bear adequate directions for use and it was not exempt from that requirement since it was a drug subject to the provisions of 503(b)(1) and its label failed to bear the correct identifying lot number as required by regulations.

DISPOSITION: 10–13–61. Default—destruction.

6748. Electronic Magnetic Model G device. (F.D.C. No. 46061. S. Nos. 26–992/93 R.)

QUANTITY: 3 devices at Ontario, Calif.

SHIPPED: 4–11–50 and 4–11–53, from Tiffin, Ohio.

RESULTS OF INVESTIGATION: The article was a suitcase-type unit which on opening displayed a control panel and detector plates. The control panel contained an array of switches, dials, push buttons, electrode terminals, and indicator lights. The electronic components within the case formed a power supply, oscillator, and amplifier for the detection and/or operation of hertzian waves.

LIBELED: 7–7–61, S. Dist. Calif.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use in the diagnosis or treatment of any disease conditions, and it was not feasible to devise any directions for use because the article was worthless for any medical purposes.

DISPOSITION: 8–16–61. Default—delivered to the Food and Drug Administration.

6749. Electronic Magnetic Model G device. (F.D.C. No. 46065. S. No. 25–436 R.)

QUANTITY: 1 *Electronic Magnetic Model G device* at Yucaipa, Calif.

SHIPPED: 6–27–60, from Tiffin, Ohio, by L. L. Roby Manufacturing Corp.

LABEL IN PART: (Front) "Electronic Magnetic Model G" and (back) "Manufactured by L. L. Roby Manufacturing Corp. Tiffin, Ohio."

ACCOMPANYING LABELING: One instruction leaflet entitled "Electronic Magnetic Instrument Model G."

RESULTS OF INVESTIGATION: The article was a suitcase-type unit which on opening displayed a control panel and detector plates. The control panel contained an array of switches, dials, push buttons, electrode terminals, and indicator lights. The electronic components within the case formed a power supply, oscillator, and amplifier for the detection and/or operation of hertzian waves.

LIBELED: 7–7–61, S. Dist. Calif.

CHARGE: 502(f)(1)—when shipped and while held for sale, the labeling of the article failed to bear adequate directions for use in the diagnosis or treatment of disease conditions, and it was not feasible to devise any directions for use because the article was worthless for any medical purposes.

DISPOSITION: 8–16–61. Default—delivered to the Food and Drug Administration.

DRUG FOR VETERINARY USE

6750. Sulfonamide boluses. (F.D.C. No. 46426. S. No. 84–721 R.)

QUANTITY: 24 ctns., each containing 50 boluses, at New York, N.Y., in possession of West-Ward, Inc.

SHIPPED: 3–9–61, from Philadelphia, Pa., by Richlyn Laboratories, Inc.

LABEL IN PART: (Ctn.) "50 boluses three sulfonamides each bolus contains: sulfathiazole 80 grains sulfanilamide 80 grains sulfamethazine 80 grains warning: * * * dosage: * * * West-Ward Inc. Distributor New York, N.Y."

RESULTS OF INVESTIGATION: Analysis of the article showed that it contained essentially the declared amount of sulfonamide, and that the article did not disintegrate within a time period that would permit effective utilization of the drug for the intended purposes.

The label on the cartons had been placed there by the dealer.

LIBELED: 9–6–61, S. Dist. N.Y.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess; and 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use in that it did not state the conditions to be treated or the species of animals to be treated.

DISPOSITION: 10–6–61. Default—destruction.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS FOR HUMAN USE

6751. Ferrous sulfate tablets. (F.D.C. No. 46147. S. No. 10–357 R.)

QUANTITY: 2 drums containing a total of approximately 82,000 tablets at Syracuse, N.Y.

SHIPPED: 2–8–61, from Philadelphia, Pa., by Richlyn Laboratories, Inc.

LABEL IN PART: "42000 E.C. Red Ferrous Sulfate USP Each Tablet Contains 5 Grains Ferrous Sulfate Equivalent to 1 Grain (64 mg.) of Metallic Iron * * * Lot No. 25905 Richlyn Laboratories, Philadelphia, Pa."

LIBELED: 8–2–61, N. Dist. N.Y.

CHARGE: 501(b)—when shipped, the article purported to be and was represented as *ferrous sulfate tablets*, a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the standard set forth in such compendium; and 502(a)—the label statement "Each Tablet Contains 5 Grains Ferrous Sulfate" was false and misleading as applied to a product containing in excess of that amount of ferrous sulfate per tablet.

DISPOSITION: 9–19–61. Default—destruction.

6752. Barium sulfate. (F.D.C. No. 46418. S. No. 96–443 R.)

QUANTITY: 2,843 10-lb. cans, at Vineland, N.J., in possession of Eastern Laboratories, Inc.

SHIPPED: 5–17–61, from New York, N.Y.

LABEL IN PART: (Can) "Barium Sulfate U.S.P. * * * Eastern Laboratories, Inc. * * * Whittaker, Clark & Daniels, Inc. New York, New York."

RESULTS OF INVESTIGATION: Analysis showed that the article failed to conform to the United States Pharmacopeia requirements for *barium sulfate*, in that it did not meet the limits for acid-soluble substances, soluble barium salts, and sulfide, when tested in accordance with U.S.P. XVI.

The article had been repacked and labeled as described by the dealer from bulk stock shipped as "Lot #333 Blanc Fixe."

LIBELED: 8–29–61, Dist. N.J.

CHARGE: 501(b)—while held for sale, the article purported to be and was represented as a drug, barium sulfate, the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality fell below the standard set forth in such compendium; and 502(a)—the article's label statement "Barium Sulfate U.S.P." was false and misleading as applied to a product which did not conform to the standards for *barium sulfate*, U.S.P.

DISPOSITION: 10–23–61. Consent—claimed by the dealer and released under bond for relabeling.

6753. Pas-C tablets. (F.D.C. No. 46526. S. No. 13–747 T.)

QUANTITY: 33 1,000-tablet btls. at Milwaukee, Wis.

SHIPPED: 10–2–61, from Chicago, Ill., by Hellwig, Inc.

LABEL IN PART: "Hellwig Pas-C Pascorbic 0.5 Grams Conjugated Para-Amino Salicylic Ascorbate Hellwig, Inc."

RESULTS OF INVESTIGATION: Analysis showed that the article was para-aminosalicylic acid. No ascorbic acid was found.

LIBELED: 11–7–61, E. Dist. Wis.

CHARGE: 501(d)(2)—when shipped, para-aminosalicylic acid had been substituted in whole or in part for conjugated para-aminosalicylic ascorbate; and 502(a)—the label statement "Conjugated Para-Amino Salicylic Ascorbate" was false and misleading when applied to an article which contained no ascorbate but was entirely para-aminosalicylic acid.

DISPOSITION: 12–4–61. Consent—claimed by Hellwig, Inc., without admitting the allegations of adulteration and misbranding, and released under bond for relabeling.

6754. Isoproterenol hydrochloride sublingual tablets. (F.D.C. No. 46342. S. No. 30–801 T.)

QUANTITY: 190 50-tablet btls. at Los Angeles, Calif.

SHIPPED: 6–25–61, from Philadelphia, Pa., by Physicians' Drug & Supply Co.

LABEL IN PART: "50 Sublingual Tablets Isoproternol Hydrochloride U.S.P. Each tablet contains: Isopropylarterenol HCl U.S.P. 15 mg. * * * Physicians' Drug & Supply Co. Philadelphia 6, Pa."

RESULTS OF INVESTIGATION: Analysis showed that the article failed to conform to the United States Pharmacopeia requirement for sublingual tablets in that it failed to disintegrate within three minutes as specified in U.S.P. XVI.

LIBELED: 9–25–61, S. Dist. Calif.

CHARGE: 501(b)—when shipped, the article purported to be and was represented as isoproterenol hydrochloride tablets, a drug, the name of which was recognized in the United States Pharmacopeia, an official compendium, and its quality differed from the U.S.P. standard for isoproterenol hydrochloride tablets; and 502(a)—the label statement "Isoproternol Hydrochloride U.S.P." was false and misleading as applied to this product which failed to conform to the U.S.P. standard for isoproterenol hydrochloride.

DISPOSITION: 10–19–61. Default—destruction.

6755. L.G.B. 12–100. (F.D.C. No. 45638. S. No. 29–800 R.)

QUANTITY: 14 individually ctnd. 10-cc. vials at Minneapolis, Minn.

SHIPPED: 12–5–60, from Decatur, Ill., by Taylor Pharmacal Co.

LABEL IN PART: (Ctn. and vial) "L.G.B. 12–100 10 cc. For Intramuscular injection Cat. No. 2185 Each cc. contains Vitamin B_{12} Activity (From Liver Injection U.S.P. Beef) Equivalent to: Cyanocobalamin 10 Mcg. * * * Vit. B_{12} Cryst 100 Mcg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 70 percent of the declared amount of vitamin B_{12}.

LIBELED: 4–25–61, Dist. Minn.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statement "Each cc. contains Vitamin B_{12} Activity (From Liver Injection U.S.P. Beef) Equivalent to: Cyanocobalamin 10 Mcg. * * * Vit. B_{12} Cryst 100 Mcg." was false and misleading.

DISPOSITION: 6–29–61. Default—destruction.

6756. Sulfacetamide. (F.D.C. No. 45808. S. No. 17–095 R.)

QUANTITY: 1 100-lb. drum at Indianapolis, Ind.

SHIPPED: 1–16–61, from New York, N.Y.

RESULTS OF INVESTIGATION: Analysis showed that the article had a melting point of 140 degrees centigrade to 184 degrees centigrade (the National Formulary requires a melting point of 181 degrees centigrade to 184 degrees centigrade), and that the article contained an appreciable amount of sulfanilamide.

LIBELED: 6–6–61, S. Dist. Ind.; amended libel 6–15–61.

CHARGE: 501(b)—while held for sale, it was found that the article purported to be and was represented as a drug, sulfacetamide, the name of which is recognized in the National Formulary, an official compendium, and its strength, quality, and purity differed from the standard set forth in such compendium; and 501(d)(2)—it was found that sulfanilamide had been substituted in part for sulfacetamide.

DISPOSITION: 9–5–61. Default—destruction.

6757. Imitation drugs. (F.D.C. No. 45770. S. Nos. 1–857 R, 58–111/12 R.)

QUANTITY: 1 btl. containing approximately 400 tablets, and 1 btl. containing approximately 1,000 tablets consisting in part of *imitation Serpasil Tablets;* and 1 btl. containing approximately 80 tablets consisting of *imitation Equanil tablets*, at Athens, Ga., in possession of Crow's Drug Store, Inc.

SHIPPED: During 1958 and on 1–15–59, from Houston, Tex.

LIBELED: 5–4–61, M. Dist. Ga.

CHARGE: 501(d)(2)—while held for sale, *imitation Serpasil tablets* and *imitation Equanil tablets* had been substituted for Serpasil tablets and Equanil tablets; 502(a)—the label statement "Serpasil Ciba" was false and misleading as applied to the article consisting in part of an imitation of Ciba Serpasil tablets; 502(i)(2)—all of the articles were in whole or in part imitations of other drugs; and 502(i)(3)—all of the articles were offered for sale under the names of other drugs.

DISPOSITION: 9–28–61. Default—delivered to the Food and Drug Administration.

6758. Rubber prophylactics. (F.D.C. No. 45793. S. No. 80–762 R.)

QUANTITY: 43 1-gross ctns. at Ellisville, Miss.

SHIPPED: 3–14–61, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Viking Prophylactics-Super Thin Nipple End Transparent Contents ¼ Doz."

RESULTS OF INVESTIGATION: Examination of 279 prophylactics showed that 2.4 percent contained holes.

LIBELED: 5–10–61, S. Dist. Miss.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "Sold For The Prevention of Disease Only" was false and misleading as applied to an article containing holes.

DISPOSITION: 6–5–61. Default—destruction.

DRUGS FOR VETERINARY USE*

6759. Vet-Aid Mix. (F.D.C. No. 45826. S. No. 22–608 R.)

QUANTITY: 14 50-lb. bags at Orient, Iowa.

SHIPPED: 7–28–60, from Humboldt, Nebr., by the O. A. Cooper Co.

LABEL IN PART: (Bag) "Cooper—Feeds Vet-Aid Mix Manufactured by the O. A. Cooper Company, Humboldt & Beatrice, Nebraska" (tag) "Active Drug Ingredients; Oxytetracycline HCL, Terramycin .025 grams per pound Chlortetracycline HCL Aureomycin .025 grams per pound."

RESULTS OF INVESTIGATION: Analysis showed that the article contained little or no chlortetracycline hydrochloride.

LIBELED: 6–6–61, S. Dist. Iowa.

CHARGE: 501(c)—when shipped, the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess; and 502(a)—the label statement "Chlortetracycline HCL (Aureomycin) .025 grams per pound" was false and misleading.

DISPOSITION: 7–7–61. Consent—delivered to a charitable institution for use as animal feed.

6760. Chick starter (medicated). (F.D.C. No. 46479. S. No. 6–013 T.)

QUANTITY: 54 100-lb. bags at Augusta, Maine.

SHIPPED: 7–20–61, from Deposit, N.Y., by Delaware Milling Co., Inc.

*See also No. 6750.

LABEL IN PART: (Bag) "Delaware Complete Chick Starter Medicated For the prevention of Coccidiosis in Chicken * * * Active Drug Ingredient: Sulfaquinoxaline 0.015% * * * Ingredients * * * Manufactured by Delaware Milling Company, Inc. Deposit, New York."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 183 percent of the declared amount of sulfaquinoxaline.

LIBELED: 10–2–61, Dist. Maine.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Sulfaquinoxaline 0.015%" was false and misleading as applied to this article which contained more than the declared amount of sulfaquinoxaline.

DISPOSITION: 11–1–61. Default—delivered to a public institution, to be mixed with an equal amount of nonmedicated chick starter, for animal consumption.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

6761. Powdered chirata and Bhaji tablets. (F.D.C. No. 45062. S. No. 25–731 R.)

QUANTITY: 38 bags, each containing 93 to 116 lbs. of chirata, and 14 145-lb. bags of chirata; 1,704 120-tablet btls. and 116 240-tablet btls. of *Bhaji tablets*, at Glendale, Calif., in possession of New Era Tea Co.

SHIPPED: (Chirata only), between 12–10–57 and 4–22–59, from India.

LABEL IN PART: (Btl.) "Temple Bell East Indian Herbal Bhaji Tablets Bhaji Tablets Contain The Valuable Plant Chirata In Combination With Rose Petals and Maté * * * New Era Tea Company, 1736 Victory Boulevard, Glendale, California."

ACCOMPANYING LABELING: Pamphlets entitled "Temple Bells East Indian Bhaji Tablets."

RESULTS OF INVESTIGATION: The dealer commissioned the tableting of the mixture of chirata, rose petals, and maté in Los Angeles, Calif., from whence the tablets were returned to the dealer at Glendale, Calif.

LIBELED: 10–26–60, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the labeling of the articles contained false and misleading representations that the articles were adequate and effective as a treatment for purifying blood, bladder, gall bladder, liver, and kidney troubles, low blood pressure, high blood pressure, enlarged heart, conditions of the bronchial tubes, nerve disorders, nerve stabilizer, skin conditions, anemia, tiredness, habitual constipation, debility of convalescence, intermittent fevers, swelling of the hands, arthritis, pimples, irritability, insomnia, mental conditions, menopausal psychosis, menopausal syndrome, and that it would produce good health, extend physical endurance, and restore pep and energy.

DISPOSITION: On 2–17–61, a claim and answer were filed by the dealer, but were withdrawn on 12–13–61. On 1–22–62, a default decree ordering destruction was entered.

6762. Mavene wafers. (F.D.C. No. 46335. S. No. 98–350 R.)

QUANTITY: 448 cases, each containing 6 boxes, each box containing 12 5-unit vials, at Kansas City, Mo.

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*See also Nos. 6743, 6745–6747, 6751–6755, 6757, 6758.

SHIPPED: Between 5–8–61 and 7–6–61, from New York, N.Y., by Yorktown Products Corp.

LABEL IN PART: (Vial) "5 Mavene Wafers * * * Contains Magnesium Carbonate, Calcium Carbonate, Dehydrated Milk and Cream, Beef Protein*, Milk Casein, Cocoa, Coconut Oil, Sucrose, Ethyl Vanillin, Malt Extract * * * Manufactured for Yorktown Products Corp., New York, N.Y."

ACCOMPANYING LABELING: Booklet entitled "Medical Facts About Excess Acidity."

LIBELED: 9–15–61, W. Dist. Mo.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment and prevention of stomach and duodenal ulcers.

DISPOSITION: 11–1–61. Consent—claimed by the shipper and released for relabeling.

6763. Lecitabs (lecithin tablets). (F.D.C. No. 46437. S. No. 70–975 R.)

QUANTITY: 8 cases, each containing 12 90-tablet btls., 1 case, containing 10 90-tablet btls., 8 cases, each containing 12 180-tablet btls., and 3 cases, each containing 12 540-tablet btls., at Minneapolis, Minn.

SHIPPED: Between 8–27–58 and 7–21–60, from Chicago, Ill., by National Lecithin, Inc.

LABEL IN PART: (Btl.) "National Lecitabs Lecithin Tablets A Natural Food Product Highly concentrated extra rich, Soya Lecithin formula of 95% oil-free Phosphatides. Ingredients: Soya Lecithin, in a base of nonfat, dry milk solids and soy protein. Natural flavoring added. Sole Distributors: National Lecithin, Inc. Chicago 26, Ill."

LIBELED: 9–11–61, Dist. Minn.; amended libel 9–15–61.

CHARGE: 502(a)—when shipped, the label of the article bore false and misleading representations that the article was adequate and effective to promote utilization of fat and to lower blood cholesterol.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 10–31–61. Default—destruction.

6764. All-In-One capsules. (F.D.C. No. 44558. S. No. 28–918 R.)

QUANTITY: 5 cases of 72 80-capsule ctns. and 3 cases of 36 160-capsule ctns. at St. Paul, Minn.

SHIPPED: 2–2–60, from West Hempstead, N.Y., by John H. Mathis, Inc.

LABEL IN PART: (Ctn.) "All-In-One Capsules A dietary Supplement * * * Each capsule contains * * * Packed for and Distributed by State Pharmacal Co., Chicago 1, Ill."

ACCOMPANYING LABELING: Leaflet entitled "The Story of All-In-One Capsules."

LIBELED: 5–2–60, Dist. Minn.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for obesity and controlling the appetite, and that the article would give the feeling of a full, contented stomach when reducing, and would keep its consumer feeling fine while losing weight.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: On 6–3–60, John H. Mathis, Inc., filed a claim and answer. On 5–23–61, the action came on for hearing before the court, and there was no appearance on behalf of any claimant. On 1–15–62, the article was ordered condemned and destroyed.

6765. Sea salt (3 seizures). (F.D.C. No. 45534. S. Nos. 14–315/17 R.)

QUANTITY: 300 cases, each containing 24 boxes, at Columbus, Ohio, in the possession of Earl J. Edmondson, t/a Sea Salt of Columbus (distributor for United Salt Corp.); 117 boxes and 48 boxes at Columbus, Ohio, in the possession of persons to whom such boxes had been delivered by Mr. Edmondson.

SHIPPED: 1–28–61, from Houston, Tex., by United Salt Corp.

LABEL IN PART: "Admiral Natural Mineral Sea Salt Nature's Own Sea Minerals. Mfgd. by United Salt Corporation, Houston, Texas * * * The modern Salt for Modern Living."

ACCOMPANYING LABELING: Leaflets entitled "100% Sea Salt with all the natural minerals"; booklets entitled "Cal October 1960" and "The Ocean's 44 Trace Chemicals (Antidotes for Deficiency Ailments)"; a placard entitled "Here it is Sea Salt (as mentioned by Dr. Crane)"; and a newspaper clipping reading in part "Mrs. Alexander, a message by Dr. Crane."

LIBELED: 3–24–61 and 3–27–61, S. Dist. Ohio.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective in the treatment or prevention of cancer, diabetes, multiple sclerosis, myasthenia gravis, muscular dystrophy, epilepsy, asthma, arthritis, insanity, deficiency ailments, allergies, Parkinson's disease, arteriosclerosis, schizophrenia, cataracts, cirrhosis, leukemia, pernicious anemia, psoriasis, dental caries, baldness, sterility, goiter, acne, and gray hair; that the article was a "chemical smorgasbord" supplying significant amounts of minerals necessary for body glands and organs to provide good health; that the article would rejuvenate endocrine glands, reactivate pigment cells in the skin, and act as a "vaccinate" against so-called deficiency diseases; that it was beneficial for growth, lactation and reproduction; that the article was a complete and balanced salt, supplying significant amounts for all the trace minerals and essential minerals for special dietary and therapeutic purposes; and that all the trace minerals in the article have been established as essential and important to good health.

DISPOSITION: 11–7–61. Default—destruction, except for a portion of the article which was delivered to the Food and Drug Administration.

6766. Delamer minerals in sea water. (F.D.C. No. 46408. S. No. 25–373 R.)

QUANTITY: 33 pt. btls., 12 qt. btls., and 12 ½-gal. btls., at Phoenix, Ariz.

SHIPPED: Between 2–16–61 and 8–16–61, from Seaside, Calif., by Del Monte Laboratories.

LABEL IN PART: "Delamer Minerals in Solution Containing Calcium, Iron and Iodine in Ocean Sea Water Specially Processed * * * One teaspoonful, three (3) times daily * * * Doses for children (under 6) and pregnant or lactating women * * * Manufactured Only by Del Monte Laboratories, Monterey, California."

ACCOMPANYING LABELING: Leaflets entitled "Is Your Health Worth 10 Cents A Day," "Be Wise Mineralize Daily The Delamer Way," "Reprinted from the Seaside News-Sentinel," "The Sea and You," and "An Important Message."

RESULTS OF INVESTIGATION: Analysis showed that the article contained essentially the labeled amounts of iron and calcium.

LIBELED: 8–29–61, Dist. Ariz.

CHARGE: 502(a)—when shipped, the labeling of the article contained representations that foods are grown in mineral-depleted soils and that the user's health is jeopardized by consumption of such foods unless health is protected by use of the article; that use of the article would drive out toxins from the body and health would follow; that the addition of minerals to sea water imparted unique properties to the article; that the article was effective for the treatment of many diseases caused by mineral deficiencies; that the article was effective in delaying the aging processes; that the article was effective in preventing the bones of the aged from becoming brittle and easily broken; and that the minerals listed on the label (except iron, calcium and iodine) were active ingredients of the article; which representations were false and misleading, since they were contrary to fact, as the article was not adequate and effective as a treatment for such diseases, conditions, or purposes, and since the minerals listed on the label (except iron, calcium and iodine) were not present in amounts which had any significance when the article was taken as directed.

DISPOSITION: 11–3–61. Default—destruction.

6767. Utopia Home Mineral Bath. (F.D.C. No. 46501. S. No. 61–222 R.)

QUANTITY: 25 cases, each containing 12 cartons of 12 3-oz. envelopes, at Boise, Idaho.

SHIPPED: 6–16–61, from Seattle, Wash., by Comfort Research, Inc.

LABEL IN PART: (Envelope) "Utopia Home Mineral Bath Ingredients: Aluminum Sulfate, Magnesium Sulfate, Magnesium Carbonate, Sodium Bicarbonate, Sodium Sulfate, Potassium Sulfate, Sodium Chloride, Sodium Borate * * * Manufactured by Comfort Research, Inc. Seattle, Wash."

LIBELED: 10–18–61, Dist. Idaho.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective, because of its mineral salt composition, as a treatment for relieving pain due to arthritis, rheumatism, neuritis, nervous tension, and muscular discomforts.

DISPOSITION: 11–14–61. Default—destruction.

6768. Olbas Basle Oil, Olbas salve, and Olbas cough syrup. (F.D.C. No. 45317. S. Nos. 13–798/9 R, 13–801 R.)

QUANTITY: 769 10-cc. btls, and 99 60-cc. btls. of *Olbas Basle Oil;* 95 ⅓-oz. tubes and 197 ⅔-oz. tubes of *Olbas salve;* and 188 btls. of *Olbas cough syrup;* at South Milwaukee, Wis., in possession of Olbas Products.

SHIPPED: Between 1–28–60 and 11–12–60, from Basle, Switzerland, by Po-Ho-Co., Ltd.

LABEL IN PART: (Ctn. and btl.) "Olbas Basle Oil Oleum Basileum produced in Switzerland by the Po-Ho-Co., Ltd. Basel Ingredients: * * * Directions for use: * * * Distributed by Heidi E. Ritter, 8327 S. 13th St. South-Milwaukee, Wisconsin"; (tube) "Olbas-Salbe * * * Po-Ho-Co., A.-C. Basel 2";

and (btl.) "Only Genuine Olbas Cough-Syrup According to Dr. Ehninger Dose: * * * Ingredients: Extr. of Common Plantain, Horse Chestnut, Liquorice, Thyme, Essential Oils, Sprouts of Pine, Ammon.-Chloride, Spirit, Syrup prepared with unrefined sugar. Net Contents 120 cc. Produced in Switzerland by the Po-Ho-Co., Ltd. Basel 20. Distributed by: Heidi E. Ritter, 8327 S. 13th St., South Milwaukee, Wisconsin."

ACCOMPANYING LABELING: Leaflets entitled "Olbas Mode of Action."

RESULTS OF INVESTIGATION: The cough syrup was shipped in a concentrated form and prepared in finished form locally for the dealer. The labels for such article and leaflets were furnished by the shipper.

LIBELED: 12–29–60, E. Dist. Wis.

CHARGE: All articles, 502(a)—when shipped, the labeling contained false and misleading representations that the articles were adequate and effective to effect beneficial changes in body metabolism, improve all glandular functions, increase flow of lymph, increase white blood corpuscles, improve digestion, and promote assimilation; and as an adequate and effective treatment of catarrhal inflammations, bronchitis, asthma, pharyngitis, anorexia, digestive disorders, gallbladder diseases, kidney malfunctions and diseases, rheumatism, gout, corpulence, skin diseases, toothache, cardialgia, nervous diseases, seasickness, colds, headaches, neuralgia, migraine, sciatica, depression, earache, and many other diseases, symptoms, and conditions; and *Olbas salve*, 502(c)—when shipped, the information required by the Act to appear on the label, namely, the common or usual names of the active ingredients contained therein, was not prominently placed on the label with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render such information likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

DISPOSITION: 2–6–62. Heidi E. Ritter, claimant, having consented to a decree of condemnation without admitting any of the allegations contained in the libel, judgment of condemnation was entered and the articles were released for relabeling.

6769. 3-Minute Balm. (F.D.C. No. 45719. S. No. 62–452 R.)

QUANTITY: 664 2-oz. btls. at Morehead, Ky.

SHIPPED: 3–15–61, from Detroit, Mich., by Hunt Bros. Products.

LABEL IN PART: (Btl.) "Hunt Bros. Products Balm 3 Minutes Directions * * * manufactured by Hunt Bros."

ACCOMPANYING LABELING: (Leaflet) "Hunt's 3 Minute Balm Directions * * * Hunt Bros. Products 5685 15th Street, Detroit 8, Mich."

LIBELED: 4–13–61, E. Dist. Ky.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for headache, sinusitis, soreness, lameness, stiffness, stiff neck, and any kind of muscular ache.

DISPOSITION: 10–18–61. Default—destruction.

6770. Protein supplement. (F.D.C. No. 45949. S. No. 53–728 R.)

QUANTITY: 82 365-tablet btls., and 2 drums containing a total of 32,500 tablets, at Minneapolis, Minn., in possession of Nu-Age Corp.

SHIPPED: 11–4–60, from St. Louis, Mo.

LABEL IN PART: (Drum) "S.C. Green w/Mint Flavor" and (btl.) "Formula 13 Protein Supplement * * * Nu-Age, Box 5816, Minneapolis 19, Minn. 6287."

ACCOMPANYING LABELING: Additional bottle labels.

RESULTS OF INVESTIGATION: The tablets were shipped in bulk and bottled and labeled by the dealer.

LIBELED: 6–19–61, Dist. Minn.

CHARGE: 502(a)—while held for sale, the repack label contained false and misleading representations that the article was adequate and effective to promote growth in children; to build vitality and endurance for all age groups; to develop athletic physiques; and to lose and to gain weight.

The libel alleged also that the article was misbranded under the provisions of the law relating to foods, as reported in notices of judgment on foods.

DISPOSITION: 7–31–61. Default—destruction.

6771. Cernelle Pollitabs. (F.D.C. No. 44999. S. No. 45–762 R.)

QUANTITY: 2,000 100-tablet btls. at Maitland, Fla., in possession of Poll-N-Co., Inc.

SHIPPED: 8–9–60, from Vegeholm, Sweden.

LABEL IN PART: (Btl.) "Cernelle Pollitabs A special dietary supplement containing a natural source of vitamin B-12 * * * Each tablet contains: 50 mgm Cernelle-Pollen 20 mgm Cernitin (Extract of pollen) Each tablet supplies 2 micrograms of vitamin B_{12}. * * * Distributed by Poll-N-Co., Inc., Maitland, Florida Made and packaged in SWEDEN by AB Cernelle, Vegeholm, Sweden."

ACCOMPANYING LABELING: Pamphlets entitled "Pollitabs" and "The Wonders of Pollen."

RESULTS OF INVESTIGATION: The accompanying labeling was prepared on behalf of Poll-N-Co., Inc.

LIBELED: 10–6–60, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of pernicious anemia; retarded growth in children, loss of appetite, weakness, neurologic disorders (including diabetic and alcoholic neuritis), ailments of the skin, nutritional anemia, and to strengthen blood, promote growth and health, and produce energy.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in food notices of judgment.

DISPOSITION: On or about 10–25–60, Poll-N-Co., Inc., filed a claim to the article and an answer to the libel. The claimant and the government filed written interrogatories which were answered in part and objected to in part by both parties.

On 11–6–61, a consent decree providing for the condemnation and destruction of the article was filed.

6772. Vitamin A capsules. (F.D.C. No. 45263. S. No. 20–341 R.)

QUANTITY: 400 60-capsule btls. at Detroit, Mich., in possession of Balance, Inc.

SHIPPED: The vitamin A and gelatin ingredients of the article were shipped into Michigan on (vitamin A) 6–28–60, from Rochester, N.Y.; and (gelatin) on 8–11–59, from Woburn, Mass.

LABEL IN PART: "Balance * * * 60 Capsules * * * a compound of animal protein and natural Vitamin A * * * Active Ingredients: Vitamin A 10,000 Units Animal Protein 10 Grains * * * Balance Inc. Detroit, Mich."

RESULTS OF INVESTIGATION: The capsules were manufactured, packed, and labeled for the dealer after the above-mentioned ingredients had been shipped as described above.

LIBELED: 12–5–60, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the label of the article contained the false and misleading statement "the safest, surest and most helpful oral medication ever compounded for common foot and leg troubles," and also contained false and misleading representations that the article was an adequate and effective treatment for and preventive of varicose veins, circulatory ailments, chronic and senile hyperkeratosis (corns and callus formation), leg and foot cramping and weakness, and improper nail growth.

DISPOSITION: 12–12–61. Consent—claimed by Balance, Inc., and released for relabeling.

6773. Coach-Aid Special Formula pills, and Coach-Aid Stim-O-Stam Food Supplement tablets. (F.D.C. No. 46563. S. Nos. 30–658/9 R.)

QUANTITY: 66 200-tablet cans of Stim-O-Stam Food Supplement, and 40 500-tablet cans of Special Formula pills, at Birmingham, Ala.

SHIPPED: 7–27–59, from Little Rock, Ark., by Health Research, Inc.

LABEL IN PART: "Coach-Aid Stim-O-Stam Food Supplement * * * Active Ingredients: Phosphate—PH 6.5–7.0 * * * Distributed By Health Research, Inc. Hot Springs, Ark." and "Coach-Aid Special Formula N.B. Pills (Bioflavonaids With C) * * * Distributed By Health Research, Inc. Hot Springs, Ark."

LIBELED: 10–9–61, N. Dist. Ala.

CHARGE: *Coach-Aid Stim-O-Stam Food Supplement tablets*, 502(a)—when shipped, the label bore false and misleading representations that the article was adequate and effective for aiding physical endurance, lessening muscle soreness, improving physical efficiency, and aiding in preventing fatigue; and 502(e)(2)—the article was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient, since "Phosphate" was not the common or usual name of that ingredient.

Coach-Aid Special Formula pills, 502(a)—when shipped, the label of the article bore false and misleading representations that the article was adequate and effective to improve resistance to bruising and bleeding, improve capillary resistance, overcome normal capillary permeability and fragility, prevent bleeding, strengthen capillary walls, reduce healing time and severity of bruises, improve formation of connective tissue and red blood cells, promote absorption of iron from food, and promote resistance to the common cold and virus and respiratory infections.

DISPOSITION: 11–9–61. Default—destruction.

6774. Family Plan Vitafood Supplement tablets. (F.D.C. No. 46449. S. No. 2–181 T.)

QUANTITY: 212 boxes, each containing 6 60-tablet btls., at Chamblee, Ga.

SHIPPED: Between 3–8–61 and 3–28–61, from Fort Worth, Tex., by Mace Laboratories, Subsidiary of T. A. Rawson, Inc.

LABEL IN PART: (Btl.) "Family Plan Vitafood Supplement Vitamin Factors * * * Mineral Factors * * * Manufactured for Mace Laboratories * * * Fort Worth, Tex."

ACCOMPANYING LABELING: Pamphlet entitled "Family Plan"; and leaflet reading in part "What You Should Know about Vitamins * * * Dr. H. H. Beard, Nutrition Consultant, Mace Laboratories."

RESULTS OF INVESTIGATION: The dealer had had the pamphlet, entitled "Family Plan," reprinted from mimeographed sheets supplied by the shipper.

LIBELED: 9–12–61, N. Dist. Ga.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the article would maintain the body balance; promote health, the reproductive processes, and growth; tone the body; promote assimilation; and for other purposes; that it was impossible to obtain adequate amounts of vitamins and minerals in the ordinary food supplies for proper nutrition; that the article contained every known vitamin and mineral needed by growing children; and that the article complied with the United States food and drug laws.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 10–23–61. Default—destruction.

6775. Micronaire device. (F.D.C. No. 45711. S. No. 20–179 R.)

QUANTITY: 50 devices at Highland Park, Mich.

SHIPPED: 9–16–60 and 3–21–60, from Roxbury, Mass., by Precipitator Corp. of America.

LABEL IN PART: (Device) "Micronaire 450 [or "400"] Electrostatic Precipitator."

ACCOMPANYING LABELING: (Display banner) "Removes Pollen, Airborne Bacteria, Dust, Smoke, Odors"; (leaflets) "Here are the answers to questions your customers will ask about Micronaire," "Micronaire Radio and Television Commercials," and "Air Purifiers A Reprint from Consumer Bulletin Annual 1959–60"; (display cards) "Micronaire Electrostatic Air Purifier" and "Traps even tiny Airborne Particles That Slip Thru Machine Filter Types"; (booklets) "Most Efficient Method of All The Portable Air Purifier"; a business reply card and a single sheet of paper bearing the penciled words "Precipitator Corp. of America Boston, Mass."

RESULTS OF INVESTIGATION: The literature described the article as a portable box-type cabinet containing an electric motor-driven fan which caused room air to flow through an electrostatic field set up between a series of particle collection plates. The labeling stated that dust particles in the air were electrically charged and were attracted to the collection plates of opposite electrical polarity and were thus removed from the air.

LIBELED: 4–12–61, E. Dist. Mich.; amended libel 4–18–61.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for relieving sufferers of hay fever, sinus, asthma, and airborne allergies; that the article would remove from the air 99.2% of such airborne impurities as dirt, dust, and pollen and that the article eliminated pollens from the air before they reached the room occupant.

DISPOSITION: 5–15–61. Consent—claimed by the Precipitator Corp. of America and relabeled.

6776. Abunda Beauty device. (F.D.C. No. 45464. S. No. 68–643 R.)

QUANTITY: 34 individually cartoned devices and 3,625 plastic containers at Fort Worth, Tex.

SHIPPED: 11–7–60 and 11–22–60, from Menlo Park, Calif., by Pam Pro Plastics.

LABEL IN PART: (Ctn.) "Abunda Beauty by Abunda Products 20 Forty First Avenue, San Mateo, Calif."

ACCOMPANYING LABELING: Pamphlets entitled "Abunda Beauty . . . New . . . Exciting . . . Revolutionary" and "Abunda Hydro Massage Bosom Beauty."

RESULTS OF INVESTIGATION: Investigation indicated that the device was a plastic cup-shaped device with a water hose attachment. In use the cup was intended to be placed over the female breast with the hose attachment connected to the household water service. The water was caused to be diffused or "swirled" in passing through a perforated disc in the cup base. The swirling water within the cup reportedly served to massage the bust.

LIBELED: 2–16–61, N. Dist. Tex.

CHARGE: 502(a)—when shipped, the name of the device "Abunda Beauty" and its labeling contained false and misleading representations that the article was adequate and effective for awakening and increasing bosom beauty; encouraging bosom perfection; restoring, healing, and revitalizing the tissues of the bosom; increasing circulation of the bust; providing cell nourishment to firm the tissues; and for providing an abundant bust through hydrotherapy.

DISPOSITION: 10–30–61. Default—destruction.

6777. Erasurage device. (F.D.C. No. 46092. S. No. 69–026 R.)

QUANTITY: 44 envelopes of *Erasurage devices* at Chicago, Ill.

SHIPPED: 11–1–60, from Pasadena, Calif., by Erasurage.

LABEL IN PART: (Envelope) "Erasurage 'The Way to Beauty'."

ACCOMPANYING LABELING: Leaflet in envelope entitled "Erasurage The Way To Youth."

RESULTS OF INVESTIGATION: Examination showed that the article was a net-like arrangement of bands of elastic and rubber sections formed to fit under the chin, across the forehead, and over the head.

LIBELED: 7–21–61, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the name "Erasurage" and certain statements in the accompanying labeling represented and suggested that the article was adequate and effective for retarding and preventing facial lines, wrinkles, double chins, sagging cheeks and muscles, restoring facial beauty and contours, lifting and replacing sagging muscles, and removing signs of facial strain and tension, which name and statements were false and misleading since the article was not adequate and effective for such purposes; and 502(b)(1)—the articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: 8–15–61 and 8–17–61. Default—delivered to the Food and Drug Administration.

6778. Figuremaker device. (F.D.C. No. 45889. S. No. 85–067 R.)

QUANTITY: 3 devices at Memphis, Tenn.

SHIPPED: 2–26–61 and 3–6–61, from Jacksonville, Fla., by John McDonald.

LABEL IN PART: "Figuremaker."

ACCOMPANYING LABELING: Leaflets entitled "For Your Figuremaker Instructions"; leaflets on North Florida Medical Laboratories letterhead, reading in part, "On This Date a Basal Metabolism Test"; and leaflets entitled "For You . . . A Miracle of Modern Medical Research Figuremaker Electronic Active Exercise."

RESULTS OF INVESTIGATION: The device was a suitcase-type container approximately 12" x 16" x 4" containing a number of electrodes, electrode cables, rubber straps, control panel and power supply. The control panel labeled "Figuremaker" contained a pilot light, two switches, and four control dials (one for each set of electrodes). The power supply was an electronic circuit which produced the electrical pulses applied to the electrodes.

The leaflet entitled "For Your Figuremaker Instructions" was enclosed in the case with the device.

LIBELED: 5–15–61, W. Dist. Tenn.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for aiding in providing figure perfection; firming and tightening muscle structure of the body; lifting and forming the female breast; eliminating hip and thigh bulges; reducing weight and decreasing girth measurements; tightening muscles under the eyes and chin; and that use of the article would increase the basal metabolism rate, thereby accelerating caloric consumption and bringing about weight reduction.

DISPOSITION: 6–21–61. Default—delivered to the Food and Drug Administration.

6779. Kongo-Kit massage device. (F.D.C. No. 45530. S. No. 25–675 R.)

QUANTITY: 30 unlabeled plastic bags, each containing 2 knitted fiber gloves and 1 knitted fiber belt designated "Brisculator," at Los Angeles, Calif., in possession of Kongo-Kit Co. (Frau Ingrid Flentjen).

SHIPPED: The gloves were shipped on 4–11–60, and the belts were shipped on 10–12–60, from Hamburg, West Germany.

LABEL IN PART: (Tag attached to plastic bag) "Kongo-Kit Handknitted."

ACCOMPANYING LABELING: Leaflet enclosed in bag entitled "Beautiful Body Conditioning."

RESULTS OF INVESTIGATION: The gloves and belts were placed in the plastic bags by the dealer after shipment as described above. The belts were hemp-like, about 20" long and 5" wide. The ends of the belt were looped for convenience in holding.

The leaflets were printed locally on order of the dealer.

LIBELED: 3–24–61, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the leaflet accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for firming the skin and figure, toning the body, renewing vitality, relaxing tenseness, stimulating and toning the muscles and

nerves, smoothing the skin, increasing blood circulation, redistributing or eliminating fatty tissue, and developing the chest and lungs.

DISPOSITION: 5–2–61. Default—destruction.

DRUG FOR VETERINARY USE*

6780. Piperazine hog and poultry wormer. (F.D.C. No. 45790. S. No. 22–037 R.)

QUANTITY: 31 1-qt. btls. at Middlebury, Ind.

SHIPPED: 9–7–60, from Toledo, Ohio, by Miller Chemical Co.

LABEL IN PART: "Piperazine Hog & Poultry Wormer Active Ingredient: Each 100 cc Contains 17.08 grams of Piperazine Base Hexahydrate. * * * Directions for use–Miller's Piperazine–A Liquid Wormer For Swine & Poultry."

LIBELED: 5–5–61, N. Dist. Ind.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was adequate and effective when used as directed in treatment for removing or controlling nodular and round worms from swine and round worms (*Ascaridia galli*) from poultry.

DISPOSITION: 6–16–61. Default—destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 6741 TO 6780

PRODUCTS

*See also No. 6760.

[1] (6746) Prosecution contested. Contains memorandum and order of the court.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (6746) Prosecution contested. Contains memorandum and order of the court.

U.S. GOVERNMENT PRINTING OFFICE: 1962

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6781–6820

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve seizure proceedings in which decrees of condemnation were entered after default or consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *November 29, 1962.*

CONTENTS*

*For failure to bear a label containing an accurate statement of the quantity of the contents. See Nos. 6786, 6794, 6820; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6783, 6784, 6786, 6801 6815, 6820; cosmetics, actionable under the drug provisions of the Act, Nos. 6815–6817.

662216—62——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6781–6820

Adulteration, Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions, or by children, where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6781. Entoquel syrup and Entoquel with Neomycin syrup (2 seizure actions). (F.D.C. Nos. 46217, 46220. S. Nos. 88–031/2 R, 91–339/40 R.)

QUANTITY: 20 6-oz. btls. of *Entoquel syrup* and 21 6-oz. btls. of *Entoquel with Neomycin syrup* at Baltimore, Md.; 44 6-oz. btls. of *Entoquel syrup* and 59 6-oz. btls. of *Entoquel with Neomycin syrup* at Jamaica, Queens, N.Y.

SHIPPED: Between 2–6–61 and 2–10–61, from Kenilworth, N.J., by White Laboratories, Inc.

LABEL IN PART: "Entoquel Syrup (Thihexinol Methyl Bromide) * * * Each Teaspoon (5 cc) contains * * * Thihexinol Methyl Bromide – 5 mg. Alcohol – 1%" and "Entoquel With Neomycin Syrup * * * Each Teaspoon (5 cc) contains * * * Thihexinol (Entoquel) – 5 mg. Neomycin (from the sulfate) – 50 mg. Alcohol – 0.5%."

ACCOMPANYING LABELING: A promotional form letter mailed on or about 4–10–61, addressed to "Dear Doctor"; a promotional folder mailed on or about 4–27–61, entitled "Are opiates now outmoded in pediatric diarrhea?"; and a promotional folder mailed in June or July 1961, entitled "Are opiates now outmoded in pediatric diarrhea?" with a picture of an infant and a bottle of paregoric on the cover.

LIBELED: 8–1–61, Dist., Md., and E. Dist, N.Y.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the articles was false and misleading:

(1) in that the promotional form letter entitled "Dear Doctor" represented that the drugs would successfully treat diarrhea which threatened pediatric patients, without side effects, which representations were contrary to fact;

(2) in that the promotional folder mailed on or about April 27, 1961, represented that the drugs "acts almost exclusively to inhibit gastro-intestinal motor function and does not interfere with gastric secretion, digestive processes, or produce other undesirable atropine-like effects when given in the recommended dosage" and that "the only side effect noted was a mild, more or less transient flushing of the skin," which representations were contrary to fact; and

(3) in that the promotional folder entitled "Are opiates now outmoded in pediatric diarrhea?" with a picture of an infant and a bottle of paregoric on the cover, mailed to physicians in June or July 1961, represented that the articles stopped diarrhea rapidly without side effects; that it did not interfere with gastric secretion, digestive processes, or produce other undesirable atropine-like effects, and that the sole side effect noted in the use of the drugs was a mild flushing of the skin, which representations were contrary to fact; 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and they were not exempt from the requirement that the articles bear such directions for use since the promotional material for the new drugs was not the same as, or substantially the same as, the labeling authorized by the effective new drug applications; and 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, since the effective new drug application filed with respect to the articles did not apply to the conditions for which the articles were promoted to the medical profession, namely,

(a) in a promotional form letter mailed to physicians on or about April 10, 1961, addressed to "Dear Doctor," the drug was offered for the treatment of complications of severe pediatric diarrhea—dehydration, electrolyte imbalance, weight loss, pale, ashen skin, sunken fontanel, distended abdomen and constant crying; and

(b) in a promotional folder entitled "Are opiates now outmoded in pediatric diarrhea?" mailed to physicians on or about April 27, 1961, the drug was offered for nonspecific digestive upsets and for nausea and vomiting, which labeling representations differed materially from the labeling claims permitted by the effective new drug application.

DISPOSITION: 8-30-61 and 9-6-61. Default—destruction.

6782. Entoquel with Neomycin syrup. (F.D.C. No. 46219. S. No. 76-752 R.)

QUANTITY: 68 6-oz. btls. at San Leandro, Calif.

SHIPPED: 3-1-61, from Kenilworth, N.J., by White Laboratories, Inc.

LABEL IN PART: "Entoquel with Neomycin Syrup Caution: * * * White Laboratories, Inc., Kenilworth, New Jersey Dosage: * * * Each Teaspoon (5 cc) contains * * * Thihexinol (Entoquel)—5 mg. Neomycin (from the sulfate)—50 mg. Alcohol—0.5%."

ACCOMPANYING LABELING: A promotional form letter mailed on or about 4-10-61, addressed to "Dear Doctor"; a promotional folder mailed on or about 4-27-61, entitled "Are opiates now outmoded in pediatric diarrhea?"; and a promotional folder mailed in June or July 1961, entitled "Are opiates now outmoded in pediatric diarrhea?" with a picture of an infant and a bottle of paregoric on the cover.

LIBELED: 8–1–61, N. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the articles was false and misleading:

(1) in that the promotional form letter entitled "Dear Doctor" represented that the drug would successfully treat diarrhea which threatened pediatric patients, without side effects, which representations were contrary to fact;

(2) in that the promotional folder mailed on or about April 27, 1961, represented that the drug "acts almost exclusively to inhibit gastro-intestinal motor function and does not interfere with gastric secretion, digestive processes, or produce other undesirable atropine-like effects when given in the recommended dosage" and that "the only side effect noted was a mild, more or less transient flushing of the skin," which representations were contrary to fact; and

(3) in that the promotional folder entitled "Are opiates now outmoded in pediatric diarrhea?" with a picture of an infant and a bottle of paregoric on the cover, mailed in June or July 1961, represented that the article stopped diarrhea rapidly without side effects; that it did not interfere with gastric secretion, digestive processes, or produce other undesirable atropine-like effects, and that the sole side effect noted in the use of the drug was a mild flushing of the skin, which representations were contrary to fact;

502(f)(1)—the labeling of the article failed to bear adequate directions for use and it was not exempt from the requirement that the article bear such directions for use since the promotional material for the new drug was not the same as, or substantially the same as, the labeling authorized by the effective new drug application; and 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since the effective new drug application filed with respect to the article did not apply to the conditions for which the article was promoted to the medical profession, namely,

(a) in a promotional form letter mailed to physicians on or about April 10, 1961, addressed to "Dear Doctor," the drug was offered for the treatment of complications of severe pediatric diarrhea—dehydration, electrolyte imbalance, weight loss, pale, ashen skin, sunken fontanel, distended abdomen and constant crying; and

(b) in a promotional folder entitled "Are opiates now outmoded in pediatric diarrhea?" mailed to physicians on or about April 27, 1961, the drug was offered for nonspecific digestive upsets and for nausea and vomiting, which labeling representations differed materially from the labeling claims permitted by the effective new drug application.

DISPOSITION: 9–21–61. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6783. Various prescription drugs. (F.D.C. No. 46582. S. Nos. 63/69 T, 71/73 T.)

QUANTITY: 4,988 tablets and capsules and 42 btls. of liquid at Jacksonville, Fla., in possession of Griffin Pharmacy, Inc.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Physician's Sample" and "Physician's Trial Package."

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs repacked from physicians' samples into containers which had labels bearing the brand names of the drugs, the words "Physician's Sample," "Physician's Trial Package," or similar wording, and the names of manufacturers, packers, or distributors located outside the State of Florida. Some of the articles were prescription drugs which had not, at the time the articles were libeled, been repacked by the dealer and which bore labels similar to the other articles.

LIBELED: 10–19–61, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the words "Physician's Sample," "Physician's Trial Package," and similar wording on the labels of the articles, were false and misleading as applied to the articles then in the possession of a repacker and intended for sale, and not then intended for use as "complimentary – not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(1)—a number of the articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(2)—the labels of a number of the articles failed to bear the common or usual name of each active ingredient contained therein; 502(f)(1)—the labeling of a number of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were drugs subject to the provisions of 503(b)(1), and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the package of the drug, as required by regulations; and 503(b)(4)—a number of the articles failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11–24–61. Default—destruction.

6784. Various prescription drugs. (F.D.C. No. 46279. S. Nos. 97–376 R, 98–403/6 R.)

QUANTITY: Various quantities of tablets, capsules, and liquid, at Grand Island, N.Y., in possession of Grandyle Pharmacy, Inc.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some drugs) "Physician's Sample Not for Sale," "Special Package for the Medical Profession Only," or "Professional Sample."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians' samples into containers having labels bearing brand names indicative of manufacture outside the State of New York, and quantities of prescription drugs which were not yet repacked, originally intended for use as samples, and still in the original sample packages bearing the names and addresses of manufacturers, packers, or distributors outside the State of New York.

LIBELED: 8–22–61, W. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the statements "Physician's Sample Not for Sale," "Special Package for the Medical Profession Only," "Professional Sample," and similar wording on the labels of a number of the articles of drug were false and misleading as applied to these articles then in the possession of a repacker and intended for sale and not then intended for use as "complimentary – not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(1)—a number of the repacked articles of drug failed to bear a label containing the name and place of business of the

manufacturer, packer, or distributor; 502(e)(2)—the labels of a number of the repacked articles of drug failed to bear the common or usual name of each active ingredient contained therein; and 503(b)(4)—a number of the repacked articles of drug were subject to 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 9–29–61. Default—destruction.

6785. Various prescription drugs. (F.D.C. No. 46086. S. Nos. 50–507/18 R, 50–521/28 R.)

QUANTITY: 5,867 tablets and capsules and 1,475 btls. of liquid at Denver, Colo., in possession of Denver Drug Co.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Physician's Trial Package," "Physician's Sample," "Professional Sample," "Sample – Not To Be Sold," and "Professional Specimen."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians' samples into containers having labels bearing brand names indicative of manufacture outside the State of Colorado, and quantities of prescription drugs which were not yet repacked, originally intended for use as samples, and still in the original sample packages bearing the names and addresses of manufacturers, packers, or distributors outside the State of Colorado.

LIBELED: 7–24–61, Dist. Colo.

CHARGE: 502(a)—while held for sale, the statements "Physician's Trial Package," "Physician's Sample," "Professional Sample," "Sample – Not To Be Sold," "Professional Specimen," and similar wording on the labels of the articles not yet repacked were false and misleading as applied to the articles then in the possession of a repacker and intended for sale and not then intended for use as "complimentary – not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(f)(1)—the labeling of a number of the repacked articles failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot number from which it was possible to determine the complete manufacturing history as is required by regulations; and 503(b)(4)—the repacked articles of drug were subject to 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10–6–61. Default—destruction.

6786. Various prescription drugs. (F.D.C. No. 46206. S. No. 59–038 R.)

QUANTITY: Approximately 3,000 pkgs. at Atlanta, Ga., in possession of Crews Drug Co., Inc.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample," "Physician's Sample," "Complimentary," "Professional Trial Package," "Professional Sample Not to Be Sold," "Clinical Trial Supply," and "Physician's sample not to be sold."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked by Crews Drug Co., Inc., from physicians' samples into containers having labels bearing brand names indicative of manufacture

outside the State of Georgia, and quantities of prescription drugs which were not yet repacked, originally intended for use as samples, still in the original sample packages bearing the names and addresses of manufacturers, packers, or distributors located outside the State of Georgia.

LIBELED: 7–28–61, N. Dist. Ga.

CHARGE: 502(b)—while held for sale, the repacked articles failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(f)(1)—their labeling failed to bear adequate directions for use and they were not exempt from that requirement since the articles were subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history as required by regulations; 503(b)(4)—the articles were subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription." and 502(a)—while held for sale, the sample legend on the unrepacked articles was false and misleading as applied to the articles then in the possession of a repacker and intended for sale and not then intended for use as "complimentary–not to be sold" samples for physicians and others lawfully engaged in dispensing prescription drugs.

DISPOSITION: 9–19–61. Default—destruction.

6787. Pluraxin vitamin capsules. (F.D.C. No. 45839. S. No. 61–959 R.)

QUANTITY: 36 100-capsule btls. at Wichita, Kans.

SHIPPED: Between 11–11–58 and 8–1–60, from New York, N.Y.

LABEL IN PART: "Pluraxin High Potency Multiple Vitamin Mixture Therapeutice Stress Formula* Each Capsule Contains * * * Folic Acid 1.5 mg. * * * Dose: 1 or 2 capsules daily."

LIBELED: On or about 7–3–61, Dist. Kans.

CHARGE: 502(a)—while held for sale, the label statement "Therapeutic Stress Formula * * * *Formula of Food and Nutrition Board, National Research Council, Plus Vitamins A and D," was false and misleading, since it was contrary to fact; and 503(b)(4)—the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10–20–61. Default—destruction.

6788. Progeri-Lam capsules and Piri-Doxin. (F.D.C. No. 45892. S. Nos. 32–269 R, 32–271 R.)

QUANTITY: 59 30-capsule btls. of *Progeri-Lam capsules* and 139 10-cc. vials of *Piri-Doxin* at Santurce, P.R.

SHIPPED: 9–14–60 and 9–19–60, from Oceanside, N.Y., by Lambda Pharmacal Laboratories, Inc.

LABEL: (Btl.) "Lambda Progeri-Lam Hormones, Vitamins – Digestive Enzymes, Lipotropic factors, Bioflavonoids, Anti-anemia components, capillary strength factors and proteins Each capsule contains: * * * Lambda Pharmacal Laboratories, Inc. 391 Atlantic Ave., Oceanside, N.Y. * * * By Medical Prescription Only" (vial) "Lambda Piri-Doxin (B Complex) For intramuscular use Dosage: 1 cc daily * * * By medical prescription only Lambda Pharmacal Laboratories, Inc."

LIBELED: 5–16–61, Dist. P.R.

CHARGE: 503(b)(4)—when shipped, the articles were subject to 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 8–3–61. Default—destruction.

6789. Hy-Jet Wafers, Medcol Cotabs, and Medatinic tablets. (F.D.C. No. 45895. S. Nos. 31–330 R, 31–332/3 R.)

QUANTITY: 17,580 *Hy-Jet Wafers* in btls. of 12 wafers, 24 wafers, and 500 wafers; 50,000 tablets of *Medcol Cotabs* in bulk containers and an undetermined number of 100-tablet btls. of *Medcol Cotabs;* and approximately 20,000 tablets of *Medatinic tablets* in 100-tablet btls., at New Orleans, La., in possession of Medco Co., Inc.

SHIPPED: The *Hy-Jet Wafers* were shipped on 2–12–60, from Gardena, Calif., by S. O. Barnes & Son, Inc.; and the other articles were shipped by a different firm, from Memphis, Tenn., on 12–11–59 and 12–28–59.

LABEL IN PART: (Btl.) "A New Concept in Feminine Hygiene Hy-Jet Wafers * * * buffered to maintain an acid condition in the vaginal mucosa * * * Medco Company, Inc., New Orleans, Louisiana"; "100 Cotabs MEDCOL * * * Each Cotab contains: Pyrilamine Maleate 4 mg., Metapyrilene HCl 4 mg. * * * Caution:"; and "100 Tablets Medatinic 500 Mg. Each Tablet Contains: Nicotinic Acid 500 Mg. (Niacin) * * * Mfg. for Medco Co., Inc., New Orleans, La."

RESULTS OF INVESTIGATION: Analysis of the *Hy-Jet Wafers* showed that they contained boric acid and phenylmercuric borate in an effervescent base. The other articles were assumed to contain the ingredients listed on their labels. The *Medcol Cotabs* and the *Medatinic tablets* contained in the bottles had been repacked by the dealer from bulk containers shipped as described above.

LIBELED: 5–24–61, E. Dist. La.

CHARGE: 502(a)—when shipped, the label of the *Hy-Jet Wafers* contained false and misleading representations that the article was adequate and effective for the treatment of monilia, trichomonas, staphylococcus, and streptococcus infections of the vaginal tract; and 503(b)(4)—while held for sale, the label of the *Medcol Cotabs* bore the statement "Caution: Federal law prohibits dispensing without prescription," and the article was not subject to 503(b)(1); and 503(b)(4)—while held for sale, the *Medatinic tablets* were a drug subject to 503(b)(1) and their label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: *Medcol Cotabs* and *Medatinic tablets*, 6–29–61. Consent—claimed by Medco Co., Inc., and released under bond for relabeling. *Hy-Jet Wafers*, 7–14–61. Default—destruction.

6790. Vigosan tablets. (F.D.C. No. 45898. S. Nos. 32–272/3 R, 32–283/4 R.)

QUANTITY: 323 25-tablet btls. and 78 50-tablet btls. at San Juan, P.R.

SHIPPED: 3–10–61 and 4–25–61, from New York, N.Y., by Gold Leaf Pharmacal Co., Inc.

LABEL IN PART: "Vigosan * * * Gold Leaf Pharmacal Co., Inc., New Rochelle, N.Y. * * * Each tablet contains: Testosterone 2 mgm. Yohimbine HCl. 5 mgm. Vitamin E 10 mgm. Extract Damiana 60 mgm. Extract Nux Vomica 5 mgm. Dosage: One or two tablets 3 times daily."

LIBELED: 5–26–61, Dist. P.R.; amended libel 8–22–61.

CHARGE: 502(a)—when shipped, the label of the article contained false and misleading representations that the article was adequate and effective as a treatment for stimulating and rejuvenating the male glands and restoring lost vitality and vigor; 502(a)—the listing on the label of the article of yohimbine HCl, vitamin E, extract damiana, and extract nux vomica as active ingredients in the article was false and misleading since such ingredients were not therapeutically active; and 503(b)(4)—the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 9–21–61. Default—destruction.

6791. **Poly-Hemin capsules.** (F.D.C. No. 45913. S. No. 17–358 R.)

QUANTITY: 106 100-capsule btls. at Salt Lake City, Utah, in possession of Brain-Kay-McQuarrie, Inc.

SHIPPED: 6–21–60, from Long Island City, N.Y., by Robin Pharmacal Corp.

LABEL IN PART: (Btl.) "Poly-Hemin * * * Brain-Kay-McQuarrie, Inc. Salt Lake City, Utah Each Tablet contains: * * * Folic Acid 1 mg. * * * Dosage, Average adult dose one or two capsules daily with meals."

ACCOMPANYING LABELING: 4,500 additional bottle labels.

RESULTS OF INVESTIGATION: The dealer had supplied the shipper with the labels for the article.

LIBELED: 6–9–61, Dist. Utah.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment of anemias; and 503(b)(4)—the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 9–11–61. Default—destruction.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE*

6792. **Amphetamine sulfate tablets and pentobarbital sodium capsules.** (F.D.C. No. 45743. S. Nos 70–363/4 R.)

QUANTITY: Unknown quantities of tablets and capsules at Bangor, Maine, in possession of George H. Horton, M.D.

SHIPPED: Prior to 4–24–61, from outside the State of Maine.

LIBELED: 4–25–61, Dist. Maine.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and the articles were not exempt from that requirement since they were prescription drugs which were not used or dispensed by the practioner in the course of his professional practice.

DISPOSITION: 10–30–61. Default—destruction.

*See also Nos. 6781–6783, 6785, 6786.

6793. Quto-Electronic Instrument. (F.D.C. No. 45941. S. No. 61–119 R.)

QUANTITY: 1 device at Arkansas City, Kans.

SHIPPED: 5–23–60, from Tiffin, Ohio, by Electronic Instrument Co.

LABEL IN PART: (Device) "Quto-Electronic Instrument Mfd. by Electronic Instrument Co. Tiffin, Ohio Model 0–20–1 P Serial 1204."

RESULTS OF INVESTIGATION: The article was a suitcase-type unit which, on opening, displayed a control panel and detector plates. The control panel contained an array of switches, dials, push buttons, electrode terminals, and indicator lights. The electronic components within the case formed a power supply, oscillator and amplifier for the detection and/or operation of hertzian waves.

LIBELED: 6–16–61, Dist. Kans.

CHARGE: 502(f)(1)—when shipped and while held for sale, the labeling of the article failed to bear adequate directions for use and no adequate directions for the use of the article could be devised because the article was worthless for any medical purposes.

DISPOSITION: 9–29–61. Default—delivered to the Food and Drug Administration.

DRUGS FOR VETERINARY USE

6794. Aspirin tablets and phenothiazine. F.D.C. No. 46261. S. Nos. 2–976/7 R.)

QUANTITY: 1 drum, containing 3,000 tablets, and 14 100-tablet jars, of aspirin, and 1 75-lb. drum and 8 1-lb. jars, of *phenothiazine*, at Miami Springs, Fla., in possession of Paramex Veterinary Supply & Manufacturing Co., Inc.

SHIPPED: 10–7–57 and 3–7–60, from Philadelphia, Pa., and Newark, N.J.

LABEL IN PART: (Jar) "Paramex Aspirin 60 Grains U.S.P. * * * Manufactured for or by Paramex Veterinary Supply and Mfg. Co., Inc., Circle Arcade, Miami Springs, Florida", and "Paramex Phenothiazine Veterinary * * * Manufactured for or by Paramex Veterinary Supply and Mfg. Co. Inc."

ACCOMPANYING LABELING: A number of loose jar labels.

RESULTS OF INVESTIGATION: The articles in the jars were repacked and labeled by the dealer from the bulk stock shipped as described above.

LIBELED: 8–30–61, S. Dist. Fla.

CHARGE: *Phenothiazine*, 502(a)—while held for sale, the label statement (jar label) "For removing hookworms, stomach worms, large mouthed bowel worms, nodular worms, cecal worms, strangyles from horses, cows, sheep, swine and poultry," was false and misleading since the article was not effective as an anthelmintic in all conditions of all the animals mentioned; both lots, 502(b)(2)—the articles were drugs in package form and they failed to bear an accurate statement of the quantity of the contents; 502(f)(1)—the labeling of the articles failed to bear adequate directions for use; and *phenothiazine*, 502(f)(2)—the labeling failed to bear the warning statements "Warning – Do not treat lactating dairy animals" and "Caution – Consult veterinarian before using in severely debilitated animals. Individual animals are occasionally sensitive to phenothiazine."

DISPOSITION: 10–24–61. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS FOR HUMAN USE

6795. L–F–12. (F.D.C. No. 46619. S. No. 26–661 T.)

QUANTITY: 30 vials at Hobart, Ind.

SHIPPED: 7–29–61, from Chicago, Ill.

LABEL IN PART: (Vial) "30 cc. Multiple Dose Sterile High Potency L–F–12 10–10–100 Each cc represents Vit. B_{12} Activity (from Liver Inj. USP Beef) equivalent to: Cyanocobalamin 10 mcgm. fortified with Folic Acid 10 mg. – Vit. B_{12} Crystalline 100 mcgm."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 60 percent of the declared amount of vitamin B_{12}.

LIBELED: 11–6–61, N. Dist. Ind.

CHARGE: 501(c)—while held for sale, the strength of the article differed from, and its quality fell below, that which it purported or was represented to possess; and 502(a)—the label statement "Vit. B_{12} Crystalline 100 mcgm." was false and misleading as applied to a product containing less than the declared amount of vitamin B_{12}.

DISPOSITION: 1–8–62. Default—destruction.

6796. Lifolic B_{12} injection. (F.D.C. No. 46077. S. No. 18–499 R.)

QUANTITY: 82 individually ctnd. vials at Albuquerque, N. Mex.

SHIPPED: 3–27–61, from Los Angeles, Calif., by American Bio-Chemical Corp.

LABEL IN PART: (Vial and ctn.) "10 cc For Intramuscular Use Only * * * LIFOLIC—B_{12} Each cc contains: Vitamin B–12 U.S.P. 100 mcg. * * * Caution: * * * Produced for New Mexico Pharmacal Co. Albuquerque, New Mexico * * * No. 28519."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 70 percent of the declared amount of vitamin B_{12}.

LIBELED: 7–14–61, Dist. N. Mex.

CHARGE: 501(c)—when shipped, the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess; and 502(a)—the label statement "Each cc contains: Vitamin B–12 U.S.P. 100 mcg." was false and misleading.

DISPOSITION: 8–23–61. Default—destruction.

6797. Con-Care Solution. (F.D.C. No. 45847. S. No. 48–902 R.)

QUANTITY: 130 2-oz. btls. at Denver, Colo.

SHIPPED: 3–24–61, from Salt Lake City, Utah, by Con-Care, Ltd.

LABEL IN PART: "Con-Care Regular Cleaning & Wetting Solution for Contact Lenses * * * Benzalkonium Chloride U.S.P. 0.004 Percent * * * Con-Care Ltd., P.O. Box 2136, Salt Lake City, Utah."

LIBELED: 6–28–61. Dist. Colo.

CHARGE: 501(c)—when shipped, the purity and quality of the article fell below that which it purported and was represented to possess since it purported to be suitable for use in the eye and for cleaning contact lenses, whereas it was not suitable for such purpose, since it was contaminated with viable microorganisms.

DISPOSITION: 8–11–61. Default—destruction.

6798. Rubber prophylactics. (F.D.C. No. 46788. S. No. 6–911 T.)

QUANTITY: 26 gross cases of 12 ctns. each, each ctn. containing 4 pkgs. of 3 rubber prophylactics, at Charlestown, Mass.

SHIPPED: 11–7–61, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Case) "Private Stock Super Thin Prophylactics One Gross (48 pkgs. of 3) M & M Rubber Co. Kansas City, 8, Mo." and (ctn. and pkg.) "Private Stock Super Thin Prophylactics Reservoir End * * * Sold for The Prevention of Disease Only M & M Rubber Co. Kansas City 8, Mo. Contents One Dozen [or "Contents ¼ Dozen"]."

RESULTS OF INVESTIGATION: Examination showed that 3 prophylactics, or 1.04 percent of 288 prophylactics, were defective in that they contained holes.

LIBELED: 12–13–61, Dist. Mass.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statements (case) "Prophylactics" and (ctn. and pkg.) "Sold For The Prevention of Disease Only," were false and misleading as applied to an article containing holes.

DISPOSITION: 1–15–62. Default—destruction.

6799. Rubber prophylactics. (F.D.C. No. 46770. S. Nos. 12–749/52 T.)

QUANTITY: 2 drums, 306 gross each, at Chicago, Ill.

SHIPPED: 10–30–61, from Carolina, P.R., by DeCaribe Rubber Co.

LABEL IN PART: (Drum) "Tested N.E. Unstamped G–155 T–18 N–137 No. 1 [or "Tested P.E. Unstamped G–152 T–15 N–137 No. 2"] De Caribe Rubber Co. Box 6007 Loiza Sta. Santurce, Puerto Rico."

RESULTS OF INVESTIGATION: Examination showed that 3 prophylactics, or 1.5 percent of 200 (No. 1), and 4 prophylactics, or 2.0 percent of 200 (No. 2), were defective in that they contained holes or were excessively fragile.

LIBELED: 12–4–61, N. Dist. Ill.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess.

DISPOSITION: 12–29–61. Default—destruction.

6800. Rubber prophylactics. (F.D.C. No. 45805. S. Nos. 10–726/7 R.)

QUANTITY: 40 gross ctns. of plastic containers of 3 units each, and 80 gross ctns. of pkgs. of 3 units each, at Rochester, N.Y.

SHIPPED: 3–13–61, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Plastic container) "Viking transparent Prophylactics" and (pkg.) "Super thin prophylactics Private Stock."

RESULTS OF INVESTIGATION: Examination showed that 1.3 percent of the units examined contained holes.

LIBELED: 5–18–61, W. Dist. N.Y.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "Sold for the prevention of disease" was false and misleading as applied to an article containing holes.

DISPOSITION: 7–3–61. Default—destruction.

6801. Clinical thermometers. (F.D.C. No. 46208. S. No. 91–731 R.)

QUANTITY: 6 72-unit ctns. at Plainfield, N.J.

SHIPPED: 6–5–61, from New York, N.Y., by Hospital Bureau, Inc.

LABEL IN PART: (Ctn.) "6 Dozen Clinical Thermometers Oral Massa Thermometer Corp.," (envelope) "Certified Accurate Clinical thermometer C–S–1–52 Oral," and (thermometer) "Massa Oral" (plus serial numbers).

RESULTS OF INVESTIGATION: Examination showed that 25 percent of the thermometers failed to meet the requirements for accuracy specified in Commercial Standard 1–52 (CS1–52) issued by the National Bureau of Standards of the Department of Commerce.

LIBELED: 8–2–61, Dist. N.J.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess, since it did not give accurate readings; 502(a)—the label statement "Certified Accurate C–S–1–52" was false and misleading since it was contrary to fact; and 502(b)(1)—the device failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: 9–11–61. Default—destruction.

DRUG FOR VETERINARY USE

6802. Medicated feeds. (F.D.C. No. 45881. S. Nos. 62–344/5 R.)

QUANTITY: 19 50-lb. bags of *hog builder pellets*, and 157 50-lb. bags of *chick starter and grower*, at Blue Rapids, Kans.

SHIPPED: 2–12–60 and 12–13–60, from Crete, Nebr., by Crete Mills.

LABEL IN PART: (Bag) "Victor Hog Builder Pellets Medicated * * * Active Drug Ingredient: Arsanilic Acid 0.03% * * * Manufactured by The Crete Mills – Division of Lauhoff Grain Company, Crete, Nebraska" and "Victor 18% Chick Starter & Grower Medicated * * * Active Drug Ingredients: Acetyl-(Para-Nitrophenyl)-Sulfanilamide 0.03% Dibutyltin Dilaurate 0.02% Dinitrodiphenylsulfonylethylenediamine 0.02% 3-Nitro-4-Hydroxyphenylarsonic Acid 0.005% * * * Manufactured by The Crete Mills – Division of Lauhoff Grain Company – Crete, Nebraska."

RESULTS OF INVESTIGATION: Analysis showed that the *hog builder pellets* contained approximately 5 percent of the declared amount of arsanilic acid, and that the *chick starter and grower* contained approximately 50 percent of the declared amount of 3-nitro-4-hydroxyphenylarsonic acid.

LIBELED: 5–16–61, Dist. Kans.

CHARGE: 501(c)—when shipped, the strength of the articles differed from, and their quality fell below, that which they purported to possess; and 502(a)—the label statements (*hog builder pellets*) "Arsanilic Acid 0.03%" and (*chick starter and grower*) "3-Nitro-4-Hydroxyphenylarsonic Acid 0.005%" were false and misleading.

DISPOSITION: 9–29–61. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

6803. Various prescription drugs. (F.D.C. No. 46238. S. Nos. 75–187/201 R.)

QUANTITY: Approximately 750 pkgs. having an approximate total value of $1,500 at Atlanta, Ga., in possession of Crew's Apothecary.

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*See also Nos. 6781–6787, 6789–6791, 6795, 6796, 6798, 6800, 6801.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: "Physician's Sample Not To Be Sold," "Clinical Trial Supply," "Sample—Not To Be Sold," "Complimentary," or similar wording.

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs originally intended for use as samples for physicians and others lawfully engaged in dispensing prescription drugs and bearing labels containing a "complimentary – not to be sold" professional sample legend, and containing also the names and addresses of manufacturers, packers, or distributors located outside the State of Georgia.

Some of the articles were prescription drugs which had been repacked by the dealer into containers to which had been affixed labels bearing such brand names for the drugs as were indicative of their manufacture outside the State of Georgia.

LIBELED: 8–4–61, N. Dist. Ga.

CHARGE: 502(a)—while held for sale, the words "Physician's Sample," "Professional Sample," "Clinical Trial Supply," "Sample – Not To Be Sold," and similar wording on the labels of the articles, were false and misleading as applied to these articles then in the possession of a repacker and intended for sale and not then intended for use as "complimentary – not to be sold" samples for physicians and others lawfully engaged in dispensing prescription drugs.

DISPOSITION: 10–3–61. Default–destruction.

6804. Lange's herbal tablets and herb tea. (F.D.C. No. 45750. S. Nos. 55–991/8 R.)

QUANTITY: 78 btls. of *LGB–4 tablets*, 29 btls. of *KB–5 tablets*, 47 btls. of *D–7 tablets*, 41 btls. of *H–9 tablets* and 37 btls. of *HB–14 tablets*, each btl. containing 120 tablets; 120 100-tablet btls. of *sarsaparilla*; 88 3½-oz. pkgs. of *sarsaparilla tea;* and 94 2-oz. pkgs. of *huckleberry leaves tea*, at Portland, Oreg., in possession of Nu Vita Foods.

SHIPPED: Prior to 3–9–61, from outside the State of Oregon.

LABEL: (Btl.) "Lange's Herbal Beverage Tablets. LGB–4 * * * Distributed by Nu Vita Foods * * * Contains 17 herbs. * * * Has a mild laxative action * * * Warning": (btl.) "Lange's Herbal Beverage Tablets KB–5 * * * Distributed by Nu Vita Foods * * * Contains 16 herbs known for their traditional value"; (btl.) "Lange's Herbal Beverage Tablets D–7 One tablet makes a bracing cup of tea * * * Distributed by Nu Vita Foods * * * Contains 16 herbs * * * Has a mild laxative action. Warning"; (btl.) "Lange's Herbal Beverage Tablets H–9 * * * Distributed by Nu Vita Foods * * * Contains 18 herbs * * * Has a mild laxative action. Warning"; (btl.) "Lange's Herbal Beverage Tablets HB–14 * * * Contains 16 Herbs * * * Has a mild laxative action Warning; * * * Distributed by Nu Vita Company"; (btl.) "Lange's Sarsaparilla (Roots) * * * Distributed by Nu Vita Foods"; (pkg.) "SeeLect Brand Imported Sarsaparilla (Smilax Aristolochiaefolia) Herb Tea"; and (pkg.) "SeeLect Brand Imported Huckleberry Leaves * * * Herb Tea."

ACCOMPANYING LABELING: Catalogs entitled "Herbal Beverage Selected Information From Leading Herb Books For Professional Use Only" and sheets entitled "Nu-Vita Foods * * * Order Blank and Price List."

RESULTS OF INVESTIGATION: The articles, except the tea, were compressed into tablets from bulk herbs on the order of the dealer and the tablets were shipped in bulk lots to the dealer who repacked and labeled them.

The dealer also had the accompanying labeling printed and distributed to health food stores or others who requested them.

LIBELED: 5-3-61, Dist. Oreg.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the articles were an adequate and effective treatment for all liver and gallbladder conditions; would tone, cleanse, nourish the liver, kidneys, stomach, and bowels; act as an astringent healer; purify the bloodstream; act as an aid in digestion; subdue inflammation; strengthen and cleanse gallbladder; give natural mineral to the body; increase the flow of glandular secretions; aid glandular function; benefit dropsy; be an adequate and effective treatment for diabetes; reduce blood sugar count; reduce albumin in urine; feed the pancreatic glands; give natural sugar; clean and stimulate mucous membranes to a healthy active condition; allow for free flow of glandular secretion; cleanse and clear urinary channel; be an adequate and effective treatment for heart conditions; strengthen and aid heart function; assist in regulating rapid and feeble heart action; aid valvular insufficiency and heart oppressions; remove accumulations of mucus; were an adequate and effective treatment for high blood pressure; would reduce hypertension; relieve nervous strain; purify and cleanse; relieve nerve spasm due to excess acid in the blood stream; neutralize acid; give tone to blood and strengthen blood veins; relieve inflammation and decay of body cells; help purify blood stream; be an adequate and effective treatment for rheumatism, gout, and ringworm; an antidote for poison; for inflammation, colds, catarrh, and fever; for bleeding and hemorrhages of lungs; for hysterical and nervous conditions; and for eruptive diseases, running ears, itch, and ulcerations.

DISPOSITION: 7-17-61. Consent—claimed by E. W. Lange, t/a Nu Vita Foods, and released under bond for relabeling.

6805. Y-Min tablets, Granular Y-Min, and vitamin C tablets. (F.D.C. No. 45541. S. Nos. 55-805/7 R.)

QUANTITY: 16 340-tablet btls. of Y-Min, 6 36-oz. btls. and 7 12-oz. btls. of *Granular Y-Min*, and 13 80-tablet btls. of vitamin C, at Parma, Idaho, in the possession of Yensen Mineral Co.

SHIPPED: 12-28-60 and 1-25-61, from Los Angeles, Calif., and St. Louis, Mo.

LABEL IN PART: "340 Y-Min Tablets An Organic Mineral Vitamin Food Supplement (Complete except for Vitamin C which is in an accompanying container) * * * Distributed by The Yensen Mineral Co., Parma, Idaho. Prepared from concentrates of sea plants and green leafy vegetables, bone flour, and iron phosphate. Vitamin A made from lemon grass, Vitamin D from irradiated plant sterols. B Complex factors are as present in yeast, with Thiamine and Riboflavin added. * * * This is a concentrated Food Supplement"; "Granular Y-Min An organic Mineral Vitamin Food Supplement (Complete except for Vitamin C which is in an accompanying container). Recommended in those conditions where an additional mineral and vitamin intake is indicated. * * * Distributed by The Yensen Mineral Co., Parma, Idaho. Contains concentrates of the sea algae Macrocystis Pyrifera, Laminaria longifolia, with specially processed wheat germ, bone meal, milk minerals, iron phosphate, and brewer's yeast. Also concentrates of the fresh fruits—apple, apricot, orange, lemon, banana, tomato, with escarole, and parsley concentrates. Vitamin A from lemon grass; Vitamin D from irradiated plant sterols; Vitamins B complex

from yeast. Thiamine and riboflavin added. * * * Y-Min is a concentrated food supplement"; and "Vitamin C 80 Tablets Each tablet contains 100 milligrams (2,000 units) of Vitamin C (Ascorbic Acid) Yensen Mineral Company, Parma, Idaho * * * Dose: one to two tablets daily."

ACCOMPANYING LABELING: Leaflets entitled "information for Y-Min users" and "About Food Supplements."

RESULTS OF INVESTIGATION: The articles were shipped in bulk and repacked by the dealer.

The leaflets were prepared on order of the dealer.

LIBELED: 4–10–61, Dist. Idaho.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the articles were adequate and effective as a treatment for and preventive of wornout conditions, allergies, nervous irritability, sluggishness, dullness, listlessness and inattentiveness of children, colds, secondary anemias, dental caries, rickets, and poor bone and tooth development; and for health; to promote normal bowel movements; provide complete digestion of food; eliminate poisons through the blood stream; improve the appetite; regulate weight and growth; improve the condition of the skin, hair and brittle nails; increase mental alertness; decrease absences from school through increasing physical resistance; cultivate immunity to childhood diseases; increase energy with less fatigue; increase hemoglobin in a few days; and promote a generally satisfactory blood picture.

The libel alleged also that the articles were misbranded under the provisions of the Act relating to foods, as reported in notices of judgment on foods.

DISPOSITION: 7–12–61. Default—destruction.

6806. Coldene vitamin tonic with iron. (F.D.C. No. 45764. S. No. 82–805 R.)

QUANTITY: 400 cases, each containing 2 display ctns., each of which contained 6 individually ctnd. btls., at New York, N.Y.

SHIPPED: Prior to September 1960, from Cranbury, N.J., by Pharma-Craft Corp.

LABEL IN PART: (Btl. & btl. ctn.) "Coldene Vitamin Tonic with Iron * * * giving therapeutic amounts of vitamins important to supplement the diet of those in run-down conditions. Especially indicated for use in convalescence from colds, flu and similar illness. Each fluid oz. (2 Tablespoonfuls) contains: * * * Riboflavin (B_2) 4 mg. * * * Pharma-Craft Corporation, Distrs. Cranbury, N.J."

ACCOMPANYING LABELING: Leaflet entitled "Coldene Liquid Cold Medicine."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 68 percent of the declared amount of riboflavin.

LIBELED: 5–8–61, S. Dist. N.Y.

CHARGE: 502(a)—when shipped and while held for sale, the label contained false and misleading representations that the article was adequate and effective as a preventive of and treatment for rundown conditions; and for use in convalescence from colds, flu, and similar illness; and the name of the article "*Coldene Vitamin Tonic with Iron*" and the label statement "therapeutic tonic" were misleading since the article was not adequate and effective as a "Vitamin tonic" and it contained the vitamin B grouping and methionine, not vitamins in general.

The libel alleged also that the article was misbranded under the provisions of the Act relating to foods, as reported in notices of judgment on foods.

DISPOSITION: 7–6–61. Default—destruction.

6807. "He-Man" High-Potency Formula. (F.D.C. No. 45474. S. No. 44–040 R.)

QUANTITY: 169 24-capsule btls. and 24 60-capsule btls. at Tacoma, Wash.

SHIPPED: 10–31–60 and 12–5–60, from Portland, Oreg., by Registered Pharmaceuticals, Ltd.

LABEL IN PART: (Btl.) "HE-MAN High-Potency Formula Directions for use. Adult men only. * * * take one capsule twice a day, morning and night, preferably after meals, as a hematinic tonic and source of vitamins * * * Contains 24 [or "60"] capsules. * * * Hematinic Tonic for Men Each 2 capsules (Daily Dose) Contains: HEMOSEX (Registered Pharmaceuticals Brand Name for six hematinics, with vascular activity of niacin). * * * Enzymes and Glandular Substances * * * Amino Products * * * Minerals and Vitamins * * * in a base containing: Damiana Root 50.0 mg. Sarsaparilla Root 50.0 mg 09032 [or "09079"] Distributed by Registered Pharmaceuticals, Ltd. Portland, Oregon."

LIBELED: 2–20–61, W. Dist. Wash.

CHARGE: 502(a)—when shipped, the label contained statements such as "He-Man Hematinic for Men," "High Potency Formula," "HEMOSEX," and "Adult Men Only," which, in the manner in which they were presented, represented and suggested that the article was effective as a tonic for increasing the sexual potency and/or virility of men, which representations and suggestions were false and misleading since the article was not an effective tonic for such purposes; the label statement "with vascular activity of niacin" was misleading since the ingestion of 50 milligrams of niacin, as supplied in the recommended dosage which may cause vasodilation of the vascular system resulting in a "flushing" that is transitory and fleeting, would not result in increased virility and/or sexual potency in men; the label reference to vitamin C (ascorbic acid) as a hematinic was false and misleading since vitamin C (ascorbic acid) is not a hematinic; and the listing on the label of certain enzymes, glandular substances, amino products, minerals and vitamins, suggested and implied that the named substances were of value as a tonic for men, particularly for increasing virility and sexual potency, which suggestions and implications were false and misleading since they are contrary to fact.

DISPOSITION: 7–17–61. Default—destruction.

6808. Vitamin B_{12} injection. (F.D.C. No. 46490. S. No. 16–938 R.)

QUANTITY: 174 individually ctnd. vials at Chattanooga, Tenn.

SHIPPED: 3–8–61, from Columbus, Ohio, by Warren-Teed Products Co.

LABEL IN PART: (Ctn. and vial) "1 vial Warren-Teed 10 cc. Sterilized Solution Vitamin B–12 100 Micrograms per cc. * * * Each cc. Contains: Vitamin B_{12} (Crystalline Cyanocobalamin) 100 Micrograms * * * The Warren-Teed Products Co. Columbus, Ohio."

ACCOMPANYING LABELING: Leaflet entitled "Warren-Teed Sterilized Solution Vitamin B_{12}."

LIBELED: 10–5–61, E. Dist. Tenn.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment of neurological disorders, trigeminal neuritis, tic douloureux, trigeminal neuralgia, neuritis, herpes zoster, tabes dorsalis, nonspecific disorders characterized chiefly by pain, migraine syndrome, acute porphyria,

peripheral vascular disorders, multiple sclerosis, amyotrophic lateral disorders, amyotonia congenita, Parkinson's disease, ascending lateral sclerosis, anterior poliomyelitis, liver disease, diabetes, hypothyroidism and atherosclerosis.

DISPOSITION: 2–28–62. Default—destruction.

6809. **Vitamin B_{12} injection.** (F.D.C. No. 46064. S. No. 57–220 R.)

QUANTITY: 2 ctns., each containing 500 individually ctnd. vials, at Long Island City, N.Y.

SHIPPED: 4–27–61, from Baltimore, Md., by Bio Ramo Drug Co., Inc.

LABEL IN PART: (Vial and ctn.) "10 cc. Crystalline Vitamin B_{12} Injection U.S.P. 30 mcg. crystalline Vitamin B_{12} per cc. * * * Usual Dose: * * * (see insert) Control: 04131 Bio Ramo Drug Co., Inc., Baltimore 1, Md."

ACCOMPANYING LABELING: Leaflets entitled "Vitamin B_{12} Injection."

LIBELED: 7–10–61, E. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for sensory neuropathies, trigeminal neuralgia (tic douloureux), diabetic neuritis, alcoholic neuritis, and other neuritides.

DISPOSITION: 8–29–61. Default—destruction.

6810. **Sulf-Hydro-Sol and S–M–C (Sulfur Mineral Concentrate).** (F.D.C. No. 46266. S. Nos. 54–452/3 R.)

QUANTITY: 311 1-oz. btls. and 132 2-oz. btls. of *Sulf-Hydro-Sol* and 8 1-pt. btls. of *S–M–C* (*Sulfur Mineral Concentrate*), at Minneapolis, Minn.

SHIPPED: 7–19–61, from Salt Lake City, Utah, by Colloidal Sulphur Co., Inc.

LABEL IN PART: "Pavo * * * Sulphur Sulf-Hydro-Sol Mixture An Exceptional Non-Toxic colloidal sulphur mixture containing as active ingredients Highly reactive sulphur complexes and colloidal trace minerals, in a high potency concentrate supplying the univalent radical SH. Directions: 6 to 10 drops in water * * * before meals * * * The Pavo Co., Inc., Minneapolis, Minn." and "Pavo * * * Sulphur-Mineral S–M–C Concentrate S–M–C Colloidal Sulphur – for Bath and External use only – Contains: Calcium Polysulfides, Monosulphide, Thiosulphate, Sulphate and Polysulfide Sulfur. Directions: * * * S–M–C is a new and effective preparation which brings the benefits of the world's outstanding sulfur mineral baths into your own home in a highly concentrated form. * * * The Pavo Co., Inc., Minneapolis, Minn."

ACCOMPANYING LABELING: Leaflets entitled "A Modern Spa In Your Home," and imprinted at the bottom "The Collodal Sulphur Company, Incorporated, William A. Caudill, President, 599 Columbus Street, Salt Lake City 16, Utah."

LIBELED: 8–31–61, Dist. Minn.; amended libel 9–12–61.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the articles contained false and misleading representations that the articles, when used as directed, were adequate and effective as a treatment for rheumatoid arthritis, and certain metabolic diseases due to sulfur deficiency; and that use of the articles would stimulate metabolism, revitalize and normalize cellular metabolism, and that one could bathe and drink his way to health and beauty by use of the articles; and that *Sulf-Hydro-Sol* possessed therapeutic and special dietary properties due to the presence therein of highly

reactive sulfur complexes and colloidal trace minerals in a high potency concentrate supplying the univalent radical SH.

DISPOSITION: 10–31–61. Default—destruction.

6811. Ease diuretic tablets. (F.D.C. No. 46346. S. No. 19–801 T.)

QUANTITY: 797 112-tablet btls. at Fort Worth, Tex., in possession of Rhodes Laboratory.

SHIPPED: 6–29–61, from Bell Gardens, Calif., by Boyle & Co. Pharmaceuticals.

LABEL IN PART: "Ease Tablets A Stimulant Diuretic * * * Distributed Exclusively by Rhodes Laboratory, Ft. Worth, Texas * * * Contains Theobromine Sodium Salicylate, Oleoresin, Capsicum, Extract Buchu, Extract Uva Ursi, Extract Juniper Berries."

ACCOMPANYING LABELING: Radio scripts entitled "5 Minute Commercial," "Ease Commercial Script Hazel," and "Ease Script Alarm Alert"; and a number of Rhodes Laboratory letterheads containing testimonials, which were used in promoting sales of the article.

LIBELED: 9–28–61, N. Dist. Tex.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for backache, leg pains, rheumatic and arthritic stiffness, headaches, dizziness, nervousness, puffiness under the eyes, swelling ankles, hands, arms, and feet, excess poisonous matter in the blood, malfunction of the kidneys, bloat, bladder urgency, neuralgia, cramps, and excess weight.

DISPOSITION: 4–27–62. Consent—destruction.

6812. Cholester-Sol capsules. (F.D.C. No. 46475. S. No. 95–721 R.)

QUANTITY: 7 8,000-capsule drums, 1 3,500-capsule drum, 28 100-capsule btls., and 3 1,000-capsule btls., at Houston, Tex., in possession of Merit Pharmaceutical Co., Inc.

SHIPPED: 5–17–61, from Detroit, Mich.

LABEL IN PART: (Btl.) "Cholester-Sol 3 Capsules Contain: Choline Bitartrate 375 mg. Inositol 75 mg. Dl-Methionine 150 mg. Liver Desiccated 150 mg. Unsaturated Fatty Acids 150 mg. Vitamin B–12 USP 1.5 mcg. L-Lysine Monohydrochloride 300 mg. Vitamin C (Ascorbic Acid) 75 mg. Manufactured for Merit Pharmaceutical Company, Inc."

ACCOMPANYING LABELING: File cards entitled "Cholester-Sol Lipotropic" and reading in part, "A modern therapy for use in control of hypercholesterolemia"; and a number of repack bottle labels.

RESULTS OF INVESTIGATION: The article in the bottles was repacked and labeled by the dealer from bulk stock shipped as described above.

The file cards were printed locally on order of the dealer.

LIBELED: 10–2–61, S. Dist. Tex.

CHARGE: 502(a)—while held for sale, the name of the article "*Cholester-Sol capsules*," and statements in its labeling, were false and misleading in that they represented and suggested that the article was adequate and effective for the control of hypercholesterolemia and atherosclerosis; to reverse fatty infiltration of the liver and to prevent hepatic cell destruction; stimulate regeneration of new liver cells and generally improve liver function; increase protein utilization (make animal protein of cereal protein); for the treatment of

cirrhosis of the liver, jaundice, alcoholism, obesity, and coronary disease; and as an adjunct therapy in diabetes, whereas the article was not adequate and effective for such purposes.

DISPOSITION: 3–8–62. Consent—claimed by Merit Pharmaceutical Co., Inc., and released under bond for relabeling.

6813. Valer-Relax capsules. (F.D.C. No. 46093. S. No. 59–875 R.)

QUANTITY: 36 btls. at Seattle, Wash.

SHIPPED: 5–19–61, from Long Beach, Calif., by Professional Products Co.

LABEL IN PART: (Btl.) "50 Capsules * * * Valer-Relax A Mild Non-Habit Forming Non Toxic All Natural Relaxant For Relief of Simple States of Tension Sleeplessness Professional Products Co. Long Beach, Calif. * * * Directions * * * This is an herb food supplement and contains: Valerian Root, 390 Mg., Peruvian Bark, 9 Mg., Barberry Bark, 9 Mg., Scullcap, 9 Mg., Vervian Root, 9 Mg., Raspberry Leaves, 9 Mg., Cola Nuts, 9 Mg., Hop Leaves, 9 Mg., Liverwort Root, 9 Mg., Orange Flowers, 9 Mg. 4265 [or "4266"]."

ACCOMPANYING LABELING: Leaflets, in three different forms, all entitled "Relax With Valer-Relax"; some imprinted "Professional Products Co." and some rubber stamped "Dr. McCormick's Natural Foods Co."

LIBELED: 7–24–61, W. Dist. Wash.

CHARGE: 502(a)—when shipped, the name "Valer-Relax" falsely and misleadingly represented and suggested that the article was capable of relaxing the user; and the labeling of the article also contained false and misleading representations and suggestions that the article was an adequate and effective treatment for nervous tension, sleeplessness, tired feeling, and a host of disorders due to nervous tension; that it would control emotions, prevent heart disease and hardening of the arteries, and gas pains around the heart; that it was a natural relaxant; and that it would allay hunger pangs and thereby result in weight reduction; and the leaflet "The All Natural Herb Tranquilizer" contained false and misleading representations and suggestions that the article would accomplish the same results as the true tranquilizing drugs.

DISPOSITION: 2–12–62. Default—destruction.

6814. Nutri-Kings tablets. (F.D.C. No. 45269. S. No. 43–241 R.)

QUANTITY: 3 360-tablet btls. and 2 540-tablet btls. at Berkeley, Calif.

SHIPPED: On an unknown date, from New York, N.Y., by Universal Nutritions, Inc.

LABEL IN PART: (Btl.) "Universal Nutritions * * * Nutri-Kings Food Supplement These vitamins and minerals supplied in part from a special base of: Alfalfa Leaves, Pacific Coast Kelp, Parsley, Zein, Soy Bean and Watercress. To insure proper potencies additional vitamins and minerals were added. * * * Universal Nutritions, Inc., Dist. New York 13, N.Y."

ACCOMPANYING LABELING: Leaflets entitled "Universal Nutrition * * * Fall, 1960."

LIBELED: 12–9–60, N. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective to "Feel your Best" and "Look your Best"; bolster health and increase energy; stimulate alertness; for relief from deficiency conditions and symptoms that might sap strength and resistance; for growth,

clear, smooth, healthy skin, well-conditioned hair, and good muscles; to fight symptoms of tired blood due to nutritional deficiencies; that the iron, vitamin B_{12} and copper are essential to formation of red blood cells and for proper liver functioning; that the article was adequate and effective as a treatment for and preventive of infection; conditions and diseases affecting the eyes, skin, gums, teeth, bones, blood, muscles, nerves, heart, digestive system, circulatory system, and glands; poor circulation; vague muscle pains; sleeplessness; dull brittle hair; poor appetite; digestive difficulties; tired, weak blood; lowered resistance; poor teeth; tired, burning eyes; poor eyesight; and tiredness.

The libel alleged also that the article was adulterated and misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods, No. 27895.

DISPOSITION: Universal Nutritions, Inc., claimed the article and filed an answer. Thereafter, on or about 1–30–61, pursuant to stipulation of the parties, the case was removed to the U.S. District Court for Dist. N.J.

On or about 8–28–61, the libel was amended to allege that the article was adulterated within the meaning of 402(a) (2) (C) in that it contained an unsafe food additive.

On 11–29–61, the claimant having consented to a decree on the ground that the article was adulterated as alleged and without an adjudication of the misbranding charge, judgment of condemnation and destruction was entered. On 12–7–61, an amendment to the above decree ordered the United States marshal for the N. Dist. of Calif., to destroy the article.

6815. Eternal Youth face cream and Capillaris hair and scalp cream. (F.D.C. No. 45936. (S. Nos. 97–081/2 R.)

QUANTITY: 4 cases, 36 4-oz. btls. each, of *Eternal Youth face cream* and 144 2-oz. jars of *Capillaris hair and scalp cream*, at Lockport, N.Y.

SHIPPED: 4–11–61, from Pittsburgh, Pa., by Mare Mano, Inc.

LABEL IN PART: (Btl.) "Eternal Youth by Mare Mano Corrective Cosmetic For Wrinkles and Blackheads * * * Mare Mano, Inc., Pittsburgh, Pa. * * * Contains no heavy metals." and (jar) "Mare Mano Capillaris Cream for Falling Hair and Dandruff Vieni-Bella Cosmetic Co. Pittsburgh, Pa."

LIBELED: 6–6–61, W. Dist. N.Y.

CHARGE: *Eternal Youth face cream.* 502(a)—when shipped, the name of the article falsely represented that it was capable of causing the user to acquire and keep an everlasting, youthful appearance; the label contained false and misleading representations that the article was capable of effectively reducing wrinkles around the eyes; and that it was an adequate and effective treatment for blackheads; and 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient.

Capillaris hair and scalp cream, 502(a)—when shipped, the label contained false and misleading representations that the article was an adequate and effective treatment for falling hair, dandruff, and to restore hair; 502(b)-(1)—the label of the article failed to bear the name of the manufacturer, packer, or distributor; and 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient.

The libel alleged also that *Eternal Youth face cream* was adulterated under the provisions of the Act relating to cosmetics as reported in notices of judgment on cosmetics, No. 213.

DISPOSITION: 7–7–61. Default—destruction.

6816. Facializer device, Derma Culture Formula No. 102, and Derma Culture Formula No. 103. (F.D.C. No. 46436. S. No. 87–086 R.)

QUANTITY: 6 devices, 46 1-oz. btls. of Formula No. 102, and 34 2-oz. btls. of Formula No. 103, at Dallas, Tex., in possession of Milady's Clinic.

SHIPPED: Between 1–1–61 and 7–10–61, from Beverly Hills, Calif., by Dermaculture, Inc.

LABEL IN PART: (Device) "Facializer Model * * * Dermaculture, Ltd. * * * Los Angeles" and "Manufactured by Gomco Surgical Mfg. Corp. Buffalo, N.Y."; and (btl.) "Derma Culture Formula No. 102 A topical detergent solution powder for use with negative galvanism. Directions: Add one oz. powder to ½ gallon water. Apply to skin with cloth packs" and "Derma Culture Formula No. 103 A topical detergent astringent solution powder to use with positive galvanism."

ACCOMPANYING LABELING: Post cards entitled "Be Skin Happy"; leaflet entitled "Dermaculture Patrons Remember These Things."

RESULTS OF INVESTIGATION: Investigation indicated that the "*Facializer*" was a device containing electric circuiting and a vacuum pump, equipped with exterior controls and mechanical and chemical components, all designed and contrived to apply galvanic electric current and vacuum to the person of the user.

"Formula No. 102" and "Formula No. 103" were white crystalline materials containing a few yellow crystals.

The accompanying labeling had been prepared by the dealer to promote use of the article.

LIBELED: 9–25–61. N. Dist. Tex.

CHARGE: *Facializer device*, 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the device was adequate and effective to remove blackheads, white heads, and tissue debris; correct enlarged pores, dry skin and oily skin; smooth wrinkles and facial lines; clear acne and pimples; increase circulation and tissue nutrition; vitalize nerve, gland, muscle and skin structure; restore natural, lovely skin health and beauty; tighten saggy cheeks and chin, and correct skin problems.

Derma Culture Formula No. 102 and *Derma Culture Formula No. 103*, 502(b)(1)—when shipped and while held for sale, the articles of drug failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and 502(e)(2)—the labels of the articles of drug failed to bear the common or usual name of each active drug ingredient.

DISPOSITION: 10–11–61. Consent—the devices were claimed by the shipper and the articles of drug were claimed by Jewel Holmes joined by her husband, Herbert W. Holmes, t/a Milady's Clinic. The articles were released to the claimants subject to the provisions of a consent decree which provided for the destruction of the articles of drug and the postcards and leaflets.

6817. Beautiqué stockings. (F.D.C. No. 46048. S. No. 14–336 R.)

QUANTITY: 1,991 individually wrapped pairs in boxes, each box containing 3 pairs, at Columbus, Ohio.

SHIPPED: 1–23–61, from Paducah, Ky., by Beautiqué Stockings, Inc.

LABEL IN PART: (Box) "Beautiqué Bathed In Precious Lotions That Beautify Your Legs."

ACCOMPANYING LABELING: Leaflet reading in part, (front) "Beautiqué Leg Stockings * * * hosiery with a built-in beauty treatment * * * that flatters your legs while massaging them with a softly scented emollient" and (back) "Beautiqué Leg Lotion . . . for Problem Legs . . . Containing Mink Oil * * * Turtle Oil * * * Royal Jelly * * * Lanolin * * * Plus the secret formula CXS which hastens the beautifying action of these precious lotions. * * * Beautiqué Stockings, Inc., Paducah, Ky. A subsidiary of Claussner-Hosiery Co."

LIBELED: 6–26–61, S. Dist. Ohio.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article contained lotions which fed the skin; rebuilt the leg tissue; preserved the bloom of youth; softened, massaged, lubricated and beautified the legs.

The libel alleged also that the article was misbranded under the provisions of the law applicable to cosmetics as reported in notices of judgment on cosmetics, No. 229.

DISPOSITION: 7–25–61 and 8–10–61. Consent—claimed by Claussner Hosiery Co., Inc., and reconditioned and relabeled.

6818. Aqua-Spa Whirlpool Bath. (F.D.C. No. 44740. S. No. 21–426 R.)

QUANTITY: 25 individually cartoned devices at Akron, Ohio.

SHIPPED: 4–22–60, from New York, N.Y., by Aqua-Spa Corp.

LABEL IN PART: (Ctn.) "1 Cat. No. ASD 100150 AQUA-SPA DELUXE WHIRLPOOL BATH * * * Good Health and Relaxation for the entire family * * * The Aqua-Spa Corp. New York 1, New York Factory: Brockton, Mass." and (device) "Aqua-Spa De Luxe Whirlpool Bath Equipped with General Electric Motor."

ACCOMPANYING LABELING: Leaflets entitled "Better Health and Relaxation for your Whole Family."

RESULTS OF INVESTIGATION: The article consisted of a vinyl-covered box, 7″ x 7″ x 19″, (with carrying handle attached to the top), enclosing an electric motor which, by means of a flexible shaft, would drive a propellor which was surrounded by a protective housing. In operation, the propellor of the device was placed in the tub or other container of water to impart a high-velocity circulatory action to the water.

LIBELED: 7–25–60, N. Dist. Ohio.

CHARGE: 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that it was an adequate and effective treatment for overcoming or relieving arthritis, circulatory disorders, orthopedic conditions, muscular spasms, spastic paralysis, infantile paralysis, spastic colitis, constipation, fibrositis, nutritional and growth disturbances, rheumatism, chronic gout, chronic bursitis, and paraplegia.

DISPOSITION: 9–20–61. Default—destruction.

6819. Exercycle device. (F.D.C. No. 44532. S. No. 14–261 R.)

QUANTITY: 30 devices at Columbus, Ohio.

SHIPPED: Between 7–23–59 and 2–1–60, from Hartford, Conn., by Exercycle Corp.

ACCOMPANYING LABELING: Leaflets entitled "How Much Do You Really Know About Keeping Physically Fit?" "Exercise is Good Preventive Medicine," "Exercise Does Keep the Weight Down," "Brain Expert Tells Why Strokes Occur," "Fats and Arteries," "Taking it Easy Called Good Way to Get Sick," "Exercise Can Help Your Heart," "10 Myths About Your Health," "Prevent Heart Attacks thru Middle Age Physical Fitness Campaign," "How to Ride Your Exercycle," and "Important to New Users!"; phonograph record "This is Your Life"; folder entitled "Basic Principles of Health and Fitness Guidance"; card entitled "Exercycle Operating Instructions"; and schematic drawing "A Dramatization of the Human System."

RESULTS OF INVESTIGATION: Examination showed the article to be a portable, bicycle-like frame device designed to remain in a fixed position when operating. The unit was equipped with an electric motor which provided power and rhythmic motions, individually or collectively, to the pedals, handlebars, and seat of the device.

LIBELED: 4–20–60, S. Dist. Ohio.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the device was an adequate and effective treatment for increasing circulation of the body, thus helping vital organs to function more efficiently; helping to counteract an increasing death rate from circulatory disorders; helping to overcome or prevent failing eyesight, intestinal disorders, nervousness, body pains and aches, heart attacks, lack of energy and vitality, and brain stroke; helping to prevent ailments not presently evident; that exercise derived from use of the *Exercycle* would reduce the blood cholesterol, thus lowering incidence of hardening of the arteries and possibly other conditions; that exercise derived from use of the *Exercycle* aided in regaining lost youth and health, controlling asthma, recovering from tuberculosis, reducing need for insulin in diabetics, and reducing complications of pregnancy; that the *Exercycle* sales representative was the best informed person on the subject of how one can stimulate his circulation; that exercise derived from use of the *Exercycle* was comparable to such "all-out" exercise as running, swimming, etc.; and that exercise derived from limited daily use of the *Exercycle* contributed significantly to weight reduction.

DISPOSITION: 6–8–61. Consent—claimed by the Exercycle Corp., and released under bond for relabeling.

DRUG ACTIONABLE BECAUSE OF OMISSION OF, OR UNSATISFACTORY, INGREDIENT STATEMENTS*

6820. Vitamin B_{12} injection. (F.D.C. No. 46484. S. No. 90–995 R.)

QUANTITY: 310 10-cc. unlabeled vials at St. Louis, Mo.

SHIPPED: 5–11–59, from Inwood, Long Island, N.Y., by Bel-Mar Laboratories, Inc.

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 990 micrograms of vitamin B_{12} per cubic centimeter.

LIBELED: 10–5–61, E. Dist. Mo.

CHARGE: 502(b)—when shipped, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of the contents; 502(e)(1)—the article failed to bear a label containing the common or usual

*See also Nos. 6783, 6784, 6815, 6816.

name of the drug; and 502(e)(2)—the article was fabricated from two or more ingredients, and it failed to bear a label containing the common or usual name of each active ingredient.

DISPOSITION: 12–22–61. Default—destruction.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U S GOVERNMENT PRINTING OFFICE:1962

D.D.N.J., F.D.C. 6821–6860

Issued December 1962

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6821–6860

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *December 5, 1962.*

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

6821. (F.D.C. No. 44270. S. Nos. 45–686/8 P.)

INFORMATION FILED: 3–1–60, W. Dist. Tex., against **Ray Carson, El Paso, Tex. (employee of a truck stop).**

CHARGE: Between 11–16–58 and 11–19–58, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 2–1–62. Sentence of 1 year in prison suspended, and probation for 1 year.

6822. (F.D.C. No. 46018. S. Nos. 8–701/3 R.)

INFORMATION FILED: 8–15–61, N. Dist. N.Y., against **Morris Kaminsky, t/a Big M Truck Stop, Town of Bethlehem, Albany, N.Y., and Dale Mackey (an employee).**

CHARGE: Between 5–25–60 and 6–6–60, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 1–15–62. Kaminsky—$450 fine and probation for 1 year; Mackey—$150 fine suspended, and probation for 1 year.

6823. (F.D.C. No. 46684. S. Nos. 95–641/3 R.)

INFORMATION FILED: 2–9–62, E. Dist. Tex., against **Arthur C. Tyer, t/a Truck Haven Cafe, Mount Pleasant, Tex.**

CHARGE: Between 5–3–61 and 6–7–61, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 3–12–62. Sentence of 3 years in jail suspended, and probation for 4 years.

6824. (F.D.C. No. 47069. S. Nos. 23–708 R, 23–712 R, 23–716/7 R.)

INFORMATION FILED: 4–20–62, W. Dist. Mo., against **Robert V. Rabinowitz, t/a Ben Casey Sundries, Kansas City, Mo.**

CHARGE: Between 5–24–61 and 6–7–61, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4–27–62. $400 fine.

6825. (F.D.C. No. 46007. S. Nos. 39–476 R, 39–740 R.)

INFORMATION FILED: 10–20–61, E. Dist. Mo., against **June Blackwell, Sullivan, Mo.**

CHARGE: Between 10–27–60 and 3–8–61, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 1–26–62. Sentence of 6 months in prison.

6826. (F.D.C. No. 46365. S. Nos. 39–720 R, 55–057 R, 66–349 R, 66–366 R.)

INFORMATION FILED: 8–21–61, W. Dist. Ark., against **Robert P. Parker, Fort Smith, Ark.**

CHARGE: Between 1–23–61 and 6–9–61, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–16–61. $200 fine and probation for 2 years.

6827. (F.D.C. No. 44966. S. Nos. 29–200 P, 74–024 P, 74–035 P, 74–043 P.)

INFORMATION FILED: 2–13–61, N. Dist. Ala., against **Edith Fay Wilder, t/a Fay's Truck Stop, Bessemer, Ala., and Trion A. Wilder.**

CHARGE: Between 8–31–59 and 10–19–59, *amphetamine sulfate tablets* and *desoxyephedrine hydrochloride tablets* were each dispensed twice without a prescription.

PLEA: Guilty by Edith Wilder to all counts and by Trion Wilder to one count involving *amphetamine sulfate tablets.*

DISPOSITION: 4–28–61. Each defendant placed on probation for 5 years, with the special condition that neither are to sell or possess any misbranded drugs.

6828. (F.D.C. No. 45224. S. Nos. 73–801 P, 73–803/5 P, 73–807/8 P, 74–140 P.)

INFORMATION FILED: 3–11–61, S. Dist. Miss., against **Ben T. Wood, t/a Truck Town Cafe & Service Station, and Howard P. Wood (an employee), Bay St. Louis, Miss.**

CHARGE: Between 6–10–59 and 10–8–59, *amphetamine sulfate tablets* were dispensed 5 times and *dextro-amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty by Ben T. Wood to all counts and by Howard P. Wood to dispensing *amphetamine sulfate tablets* 3 times and *dextro-amphetamine sulfate tablets* once.

DISPOSITION: 6–13–61. Ben T. Wood—$700 fine and suspended sentence of 6 months on each of 7 counts, to run concurrently; Howard P. Wood—$400 fine and suspended sentence of 6 months on each of 4 counts, to run concurrently. Each defendant placed on probation for 1 year, to run concurrently with sentence previously imposed in the Eastern District of Louisiana (see Drug N.J. 6282).

6829. (F.D.C. No. 46362. S. Nos. 66–274 R, 66–294 R.)

INFORMATION FILED: 8–10–61, W. Dist. Ark., against **LeRoy E. Callahan, M.D., DeQueen, Ark.**

CHARGE: Between 3–31–61 and 5–26–61, *amphetamine sulfate tablets* were dispensed twice without prescriptions.

PLEA: Guilty.

DISPOSITION: 9–25–61. $1,000 fine and probation for 2 years.

6830. (F.D.C. No. 44627. S. Nos. 15–745/6 P, 15–748 P, 63–069 P.)

INFORMATION FILED: 8–2–60, N. Dist. Ind., against **Dempsey Arnett, t/a Sand Hill Truckers Lodge, Grovertown, Ind., and Cathy Bates and George Elder (employees).**

CHARGE: Between 12–12–58 and 7–17–59, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

DISPOSITION: Defendant Arnett filed a motion for dismissal on the grounds that the information did not state an offense with sufficient certainty to permit him to prepare an adequate defense, that the information did not allege the location from which the tablets were shipped, the name of the shipper or that the defendant knew the tablets had been part of an interstate shipment. Defendant Bates also filed a motion for dismissal on the ground that her name was in fact Bates and not Bales, as alleged in the information. On 9–30–60, after consideration of the briefs of the parties, the court denied the motions but permitted the information to be amended to change the name Bales to Bates.

Thereafter Defendant Elder entered a plea of guilty to counts 1 and 2 of the information and, on October 24, 1960, was given a suspended sentence of 6 months in jail and placed on probation for 2 years.

Defendants Arnett and Bates subsequently entered pleas of guilty to count 3 and (Arnett only) to count 4. On 4–29–61, such defendants were each fined $500, plus costs. Arnett was also sentenced to serve 6 months in jail, and Bates was given a suspended sentence of 6 months in jail and placed on probation for 2 years.

6831. (F.D.C. No. 45660. S. Nos. 19–341/2 R.)

INFORMATION FILED: 7–14–61, E. Dist. Mich., against **Jerome J. Ratajczak, Detroit, Mich.**

CHARGE: Between 3–21–60 and 4–7–60, *dextro-amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 1–16–62. $250 fine and probation for 2 years.

6832. (F.D.C. No. 46385. S. Nos. 3–230 R, 45–891 R, 45–900/1 R, 45–917 R, 45–928 R, 45–934 R.)

INFORMATION FILED: 12–19–61, M. Dist. Ga., against **Deriso-Park Drugs, Inc., and Frank J. Deriso (president), Sylvester, Ga.**

CHARGE: Between 2–13–61 and 5–3–61, *dextro-amphetamine sulfate tablets* were dispensed 4 times and *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4–2–62. Each defendant fined $500.

6833. (F.D.C. No. 45209. S. Nos. 49–552 P, 49–556 P, 49–560 P, 49–571 P.)

INFORMATION FILED: 4–26–61, W. Dist. Wash., against **Myer Michael Grashin, Seattle, Wash.**

CHARGE: Between 3–9–59 and 4–28–59, *dextro-amphetamine sulfate tablets* were dispensed 3 times and *pentobarbital sodium capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2–19–62. $3,000 fine, sentence of 1 year in prison suspended, and probation for 31 months.

6834. (F.D.C. No. 45672. S. Nos. 80–421/2 P, 19–321/4 R.)

INFORMATION FILED: 6–30–61, E. Dist. Mich., against **Sunset Drugs, Inc., Saul S. Lazar (president) and Bernard C. Le Veque (pharmacist), Flint, Mich.**

CHARGE: Between 1–29–60 and 3–23–60, *dextro-amphetamine sulfate tablets*, *Achromycin V capsules*, and *Dextro-Prolongsule capsules* were each dispensed twice without a prescription.

PLEA: Nolo contendere by the corporation and by Lazar to all 6 counts of the information and by Le Veque to 5 counts.

DISPOSITION: 7–20–61. Corporation—$600 fine; Lazar—$6 fine; and Le Veque—$5 fine, all of which fines were suspended.

6835. (F.D.C. No. 46360. S. Nos. 14–750/5 P.)

INFORMATION FILED: 10–19–61, N. Dist. Ill., against **Archibald E. Baird, t/a Austin Drug & Truss Co., Chicago, Ill.**

CHARGE: Between 7–29–59 and 9–3–59, *dextro-amphetamine sulfate tablets* and *Tuinal capsules* were each dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 1–30–62. Sentenced to 90 days in jail and probation for 3 years.

6836. (F.D.C. No. 46022. S. Nos. 11–023/8 R, 11–127/8 R, 11–219/20 R.)

INFORMATION FILED: 8–22–61, W. Dist. N.Y., against **469 Monroe Pharmacy, Inc., and Maurice Liberman (president and pharmacist), Rochester, N.Y.**

CHARGE: Between 2–3–61 and 3–7–61, *Dexedrine Sulfate tablets* were dispensed 6 times, and *Seconal Sodium capsules* and *Diuril tablets* were each dispensed twice, upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 12–20–61. Corporation—$400 fine; Liberman—$200 fine.

6837. (F.D.C. No. 45564. S. Nos. 28–242/3 R, 29–135/9 R, 30–020 R.)

INFORMATION FILED: 5–31–61, W. Dist. Wis., against **Hilton Prescription Pharmacy (a partnership), Fred W. Fries (partner pharmacist), and Aloysius N. Simon (pharmacist), LaCrosse, Wis.**

CHARGE: Between 6–24–60 and 7–19–60, *Dexedrine Sulfate tablets* were dispensed 5 times (counts 1–5) and *phenobarbital tablets* were dispensed 3 times (counts 6–8), upon requests for prescription refills without authorization from the prescriber.

PLEA: Guilty by the partnership to all counts; by Fries to counts 1, 3, 5, 6, and 8; and by Simon to counts 2, 4, and 7.

DISPOSITION: 6–20–61. Partnership—$400 fine; individuals—probation for 18 months.

6838. (F.D.C. No. 44968. S. Nos. 22–339 R, 22–343/4 R, 22–346/7 R, 22–354/5 R, 23–545 R.)

INFORMATION FILED: 1–5–61, W. Dist. Mo., against **Simon H. Dolginoff, t/a Troost Drugs, Kansas City, Mo.**

CHARGE: Between 3–11–60 and 4–11–60, *Dexedrine Sulfate tablets* were dispensed 4 times and *pentobarbital sodium capsules* and *Dexedrine Spansule capsules* were each dispensed twice without prescription.

PLEA: Guilty.

DISPOSITION: 1–13–61. $1,200 fine, plus costs.

6839. (F.D.C. No. 46668. S. Nos. 23–664 R, 24–019 R, 60–981/3 R.)

INFORMATION FILED: 3–26–62, W. Dist. Mo., against **Lloyd G. Crecelius, t/a Lineville Oil Co., and Harvey M. Harkins, South Lineville, Mo.**

CHARGE: Between 3–3–61 and 3–29–61, *desoxyephedrine hydrochloride tablets* were dispensed 5 times without a prescription.

PLEA: Guilty by each defendant to 3 counts.

DISPOSITION: 4–6–62. Each defendant fined $300, plus costs.

6840. (F.D.C. No. 46384. S. Nos. 46–010 R, 57–269 R, 57–271 R, 59–101/2 R, 74–944/5 R.)

INFORMATION FILED: 11–11–61, M. Dist. N.C., against **Manlus Ray Barnhardt, t/a Rockwell Drug Co., Rockwell, N.C.**

CHARGE: Between 11–4–60 and 4–17–61, *Miltown tablets* were dispensed 3 times and *penicillin G potassium tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 2–12–62. $1,000 fine.

6841. (F.D.C. No. 45967. S. Nos. 87–520 P, 1–561 R, 1–564 R, 1–570 R, 1–572 R, 1–577 R, 1–583 R, 1–588 R, 1–591 R, 1–606 R.)

INDICTMENT RETURNED: 8–14–61, M. Dist. Ga., against **Glynn Lamar Cawley, t/a Glynn's Pharmacy, Abbeville, Ga.**

CHARGE: Between 2–8–60 and 9–27–60, *Miltown tablets* were dispensed 10 times without a prescription.

PLEA: Guilty.

DISPOSITION: 1–15–62. $200 fine.

6842. (F.D.C. No. 46677. S. Nos. 57–637 R, 57–644 R, 57–649 R, 57–655 R, 74–841 R, 74–847 R, 74–863 R.)

INFORMATION FILED: 1–25–62, S. Dist. Fla., against **Alvin Rosen, t/a Westwood Lake Pharmacy, Miami, Fla.**

CHARGE: Between 2–15–61 and 6–20–61, *Miltown tablets* were dispensed 4 times, *Equanil tablets* were dispensed once, and *Nembutal capsules* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 2–16–62. $700 fine, sentence of 1 year in prison, suspended, and probation for 1 year.

6843. (F.D.C. No. 46649. S. Nos. 59–061 R, 59–093 R, 59–095 R, 59–140 R, 74–950/1 R, 74–954 R.)

INFORMATION FILED: 12–14–61, W. Dist. N.C., against **Sterling Drug Store No. 4, Inc., Charlotte, N.C., Henry A. Hammond (vice president), and Mell C. Bishop (drug clerk).**

CHARGE: Between 1–30–61 and 4–25–61, *Miltown tablets* were dispensed 5 times upon request for a prescription refill without obtaining authorization from the prescriber, and *butabarbital sodium tablets* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 4–5–62. $750 fine against defendants jointly, and prayer for judgment continued for 2 years.

6844. (F.D.C. No. 46713. S. Nos. 74–848/9 R, 74–860/1 R.)

INFORMATION FILED: 3–16–62, S. Dist. Fla., against **Olympia Heights Pharmacy, Inc., and Michael P. Passaro (manager), Miami, Fla.**

CHARGE: Between 3–25–61 and 6–19–61, *Miltown tablets* and *penicillin G potassium tablets* were each dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 4–30–62. Each defendant fined $500.

6845. (F.D.C. No. 46358. S. Nos. 8–113 R, 34–404/5 R, 36–151 R, 36–158 R.)

INFORMATION FILED: 2–14–62, S. Dist. N.Y., against **Joseph Hochberg, t/a George Washington Chemists, New York, N.Y., and Harry Nevel (pharmacist).**

CHARGE: Between 10–31–60 and 12–6–60, *Miltown tablets* and *Metandren tablets* were each dispensed once and *Deronil tablets* were dispensed twice without a prescription, and *Miltown tablets* were dispensed once upon request for a prescription refill without obtaining authorization from the prescriber.

PLEA: Guilty by Hochberg to 2 counts; by Nevel to 4 counts.

DISPOSITION: 3–30–62. Each defendant placed on probation for 2 years.

6846. (F.D.C. No. 45221. S. Nos. 57–217 P, 57–229 P, 57–234 P, 72–525 P, 72–528 P, 72–532 P, 72–534 P, 72–561 P.)

INFORMATION FILED: 2–24–61, S. Dist. Ga., against **Tommy Durell Wooten, t/a Wooten Drug Co., Lumber City, Ga., and Noah S. Meadows (pharmacist).**

CHARGE: Between 10–20–59 and 1–11–60, *penicillin tablets* (counts 1, 2, 5, and 6) were dispensed 4 times, *Miltown tablets* (counts 3, 4, and 8) were dispensed 3 times, and *Dexedrine Sulfate tablets* (count 7) were dispensed once without a prescription.

PLEA: Nolo contendere by Wooten to all counts; and by Meadows to counts 3, 4, 5, 7, and 8.

DISPOSITION: 1–15–62. Each defendant fined $250 and placed on probation for 2 years.

6847. (F.D.C. No. 46718. S. Nos. 46–925/6 R, 46–929/30 R, 46–933 R.)

INFORMATION FILED: 3–29–62, E. Dist. Mich., against **Elmer F. Nestell, t/a Nestell's Pharmacy, Saginaw, Mich.**

CHARGE: Between 4–20–61 and 5–24–61, *penicillin tablets* and *Metandren Linguets* were each dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 4–9–62. Sentence of 6 months in jail, suspended, and probation for 1 year.

6848. (F.D.C. No. 46646. S. Nos. 59–010 R, 59–126 R, 74–958 R, 74–961 R, 75–006 R, 75–013 R.)

INFORMATION FILED: 12–14–61, W. Dist. N.C., against **Aubrey T. Humphries, t/a Hoskins Drug Co., Charlotte, N.C.**

CHARGE: Between 3–8–61 and 5–2–61, *penicillin G potassium tablets* and *Butisol Sodium tablets* were each dispensed once and *Equanil tablets* and *Miltown tablets* were each dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 4–5–62. $750 fine, and prayer for judgment continued for 2 years.

6849. (F.D.C. No. 45664. S. Nos. 45–130 P, 45–137 P, 17–612 R, 17–620 R.)

INFORMATION FILED: 6–30–61, Dist. Colo., against **Frank O. Meza, t/a Meza Gibbs Drug Store, Denver, Colo.**

CHARGE: Between 1–31–59 and 3–16–60, *secobarbital sodium capsules*, *Pentids capsules*, *Dexedrine Sulfate tablets*, and *Metandren Linguets* were each dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 12–15–61. $1,000 fine, and probation for 3 years.

6850. (F.D.C. No. 45242. S. Nos. 57–227 P, 72–484 P, 72–509 P, 72–522 P, 72–530 P, 72–547 P, 72–562 P.)

INFORMATION FILED: 6–6–61, S. Dist. Ga., against **Earle J. Yarley (pharmacist), Savannah, Ga.**

CHARGE: Between 9–18–59 and 1–12–60, *secobarbital sodium capsules* were dispensed once and *dextro-amphetamine sulfate tablets* were dispensed 6 times by refilling a prescription without obtaining authorization from the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 5–14–62. Probation for 3 years.

6851. (F.D.C. No. 45253. S. Nos. 6–342 R, 6–344 R, 6–346 R, 6–349 R, 6–354 R, 7–076 R.)

INFORMATION FILED: 6–9–61, Dist. R.I., against **Carmine J. Olivelli and Mario D. Olivelli, Providence, R.I.**

CHARGE: Between 4–11–60 and 5–4–60, *secobarbital sodium capsules* were dispensed twice, *Butazolidin tablets* were dispensed twice, and *Dexedrine Sulfate tablets* were dispensed once upon requests for prescription refills without authorization from the prescriber, and *Miltown tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 8–28–61. Each of the defendants was fined $600.

6852. (F.D.C. No. 47106. S. Nos. 31–115 R, 31–117/9 R, 31–985 R, 32–156 R, 32–158 R.)

INFORMATION FILED: 4–12–62, N. Dist. Ala., against **Caddell Drug Co. (a partnership), Decatur, Ala.**

CHARGE: Between 12–10–60 and 3–27–61, *Seconal Sodium capsules* and *Dexedrine Sulfate tablets* were each dispensed twice, and *Equinal tablets* were dispensed 3 times by refilling a prescription without obtaining authorization from the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 4–23–62. $250 fine.

6853. (F.D.C. No. 45991. S. Nos. 90–872 P, 6–421 R, 6–428/9 R, 6–641 R, 6–645 R, 6–647/8 R, 6–691 R, 6–693 R.)

INFORMATION FILED: 8–22–61, Dist. Mass., against **Richard M. Polikoff, t/a Savin Hill Pharmacy, Dorchester, Mass., and Norman Nevler (employee pharmacist).**

CHARGE: Between 2–1–60 and 5–14–60, *Nembutal capsules* were dispensed once without a prescription, *Butazolidin tablets* were dispensed 6 times, and *Seconal Sodium capsules* were dispensed 3 times, upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by Polikoff to all counts; by Nevler to 3 counts.

DISPOSITION: 11–13–61. Polikoff—$750 fine, 6 months in prison suspended, and probation for 2 years. 12–15–61. Nevler—$100 fine and 2 years probation.

6854. (F.D.C. No. 46683. S. Nos. 1–255 R, 2–015 R, 2–019 R, 2–023/4 R, 74–661 R, 74–663 R, 74–672/3 R.)

INFORMATION FILED: 3–16–62, S. Dist. Fla., against **Miami Beach Pharmacy, Inc., Jack L. Jablo (president), Jules C. Fierman (secretary treasurer), and Harry Flink (employee), Miami Beach, Fla.**

CHARGE: Between 3–6–61 and 6–13–61, *Nembutal capsules* were dispensed 5 times, and *Miltown tablets* were dispensed 4 times, by refilling a prescription without obtaining authorization from the prescriber.

PLEA: Nolo contendere by the corporation, Jablo, and Fierman to all counts; by Flink to 1 count.

DISPOSITION: 4–30–62. Corporation and Jablo each fined $1,000; Fierman and Flink each fined $500.

6855. (F.D.C. No. 45573. S. Nos. 49–606/7 P, 76–962 P, 76–968/71 P, 76–984/6 P.)

INFORMATION FILED: 6–19–61, W. Dist. Wash., against **Rolfe I. Mollett, t/a Rolfe's Drug Store, Hoquiam, Wash.**

CHARGE: Between 8–19–59 and 9–23–59, *apiol and ergot capsules* were dispensed 4 times and *Dexedrine Sulfate tablets* were dispensed once without a prescription, and *Dexedrine Sulfate tablets* were dispensed twice and *Seconal Sodium capsules* were dispensed 3 times upon requests for prescription refills without authorization from the prescriber.

PLEA: Guilty.

DISPOSITION: 8–23–61. $1,000 fine and probation for 3 years.

6856. (F.D.C. No. 45988. S. Nos. 32–887 R, 32–902 R, 32–925 R, 35–715 R.)

INFORMATION FILED: 8–14–61, Dist. N.J., against **William B. Richter, t/a Stuyvesant Pharmacy, Lyndhurst, N.J.**

CHARGE: Between 3–21–60 and 8–9–60, *Atarax tablets*, *Seconal Sodium capsules*, and *Equanil tablets* were each dispensed once upon request for a prescription refill without authorization from the prescriber, and *Butazolidin tablets* were dispensed once without any prescription.

PLEA: Guilty.

DISPOSITION: 10–13–61. $400 fine.

6857. (F.D.C. No. 46661. S. Nos. 96–862/5 R, 96–891/3 R, 96–923/4 R.)

INFORMATION FILED: 1–3–62, W. Dist. N.Y., against **Groh Corp., Rochester, N.Y.**

CHARGE: Between 2–25–61 and 3–30–61, *Diuril tablets* were dispensed 4 times. *Dexedrine Sulfate tablets* and *secobarbital sodium capsules* were each dispensed twice, by refilling a prescription without obtaining authorization from the prescriber, and *Dexedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 1–29–62. $1,800 fine, of which $1,200 was remitted.

6858. (F.D.C. No. 46381. S. Nos. 58–995 R, 59–003/4 R, 59–007/9 R, 59–012/3 R.)

INFORMATION FILED: 11–22–61, W. Dist. N.C., against **Carolina Cut-Rate Drug Store, Inc., Charlotte, N.C., Foster E. Thomas (vice president and registered pharmacist), and Rufus O. Harris (pharmacist employee).**

CHARGE: Between 3–23–61 and 5–4–61, *Equanil tablets* and *Pentids tablets* were each dispensed 4 times.

PLEA: Guilty.

DISPOSITION: 4–5–62. $750 fine against the defendants jointly.

6859. (F.D.C. No. 46731. S. Nos. 25–166/70 R, 85–787 R.)

INFORMATION FILED: 4–20–62, W. Dist. Mo., against **Gerald R. Fredman, t/a Fredman's Drugs, Kansas City, Mo., and Sanford Lerenberg (assistant manager).**

CHARGE: Between 6–10–60 and 7–8–60, *meprobamate tablets* were dispensed 3 times and *Seconal Sodium capsules* were dispensed twice upon request for a prescription refill without obtaining authorization from the prescriber, and *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty by Fredman to all counts; by Lerenberg to 2 counts.

DISPOSITION: 4–27–62. Fredman—$500 fine; Lerenberg—$200 fine.

6860. (F.D.C. No. 45986. S. Nos. 18–693 R, 18–695 R.)

INFORMATION FILED: 8–2–61, Dist. Utah, against **John R. Berntsen, t/a John R. Berntsen Pharmacy, and W. Hugh Leonard (pharmacist), Provo, Utah.**

CHARGE: Between 10–3–60 and 10–10–60, *Thorazine tablets* were dispensed twice upon requests for prescription refills without authorization from the prescriber.

PLEA: Berntsen—guilty to 2 counts; Leonard—guilty to one count.

DISPOSITION: 10–23–61. Berntsen—$400 fine; Leonard—$100 fine.

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